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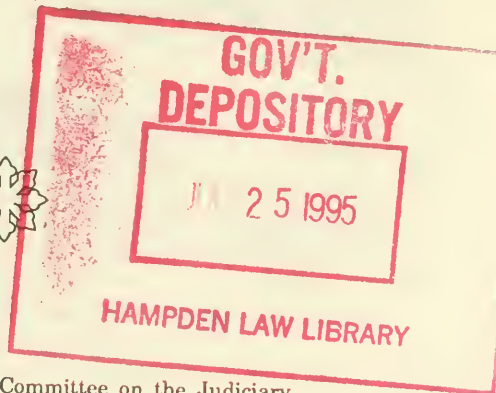
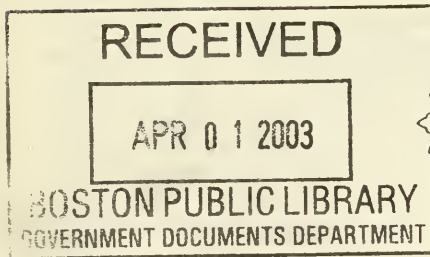
HEALTH CARE FRAUD

HEARINGS

BEFORE THE
SUBCOMMITTEE ON
CRIME AND CRIMINAL JUSTICE
OF THE
COMMITTEE ON THE JUDICIARY
HOUSE OF REPRESENTATIVES
ONE HUNDRED THIRD CONGRESS
FIRST SESSION

FEBRUARY 4 AND MAY 27, 1993

Serial No. 78



Printed for the use of the Committee on the Judiciary

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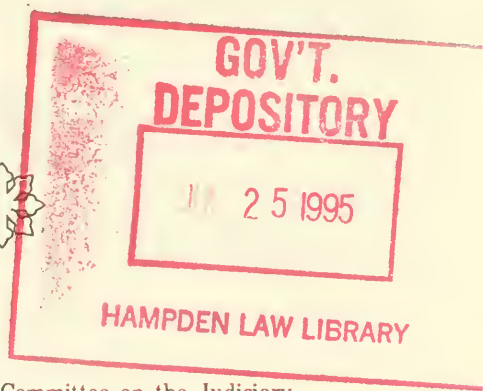
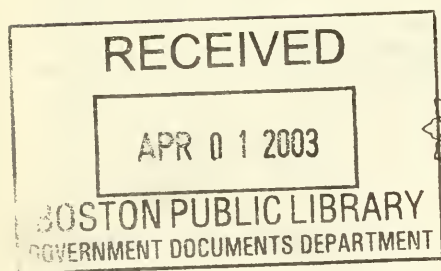
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HEALTH CARE FRAUD

THURSDAY, FEBRUARY 4, 1993

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON CRIME AND CRIMINAL JUSTICE,
COMMITTEE ON THE JUDICIARY,
Washington, DC.

The subcommittee met, pursuant to notice, at 10 a.m., in room 2226, Rayburn House Office Building, Hon. Charles E. Schumer (chairman of the subcommittee) presiding.

Present: Representatives Charles E. Schumer, Don Edwards, David Mann, F. James Sensenbrenner, Jr., George W. Gekas, Lamar S. Smith, Steven Schiff, and Jim Ramstad.

Also present: Andrew Foïs, counsel; Dan Cunningham, assistant counsel; Marie McGlone, assistant counsel; Lisa Lawler, secretary; Lyle Nirenberg, minority counsel; Ray Smietanka, minority counsel; and Mark Curtis, congressional fellow.

OPENING STATEMENT OF CHAIRMAN SCHUMER

Mr. SCHUMER. We will call this hearing to order.

First, the Chair has received a request to cover this hearing in whole or in part by television broadcast, radio broadcast, still photography or other similar methods. In accordance with committee rule 5 the permission will be granted unless there is objection.

Without objection.

First, I would like to welcome everybody here. I apologize for being a little late and for some of my Democratic colleagues who are not here. The President was supposed to address the Democratic whip organization at 9 o'clock. I waited on the edge of my seat. When he wasn't there at 5 of 10, I left. Some of my colleagues are still over there sitting on the edge of their seats.

We will begin this morning not only an investigation of the issue that is of vital importance to the health and well-being of the citizens of our country, health care fraud, but today we also launch the subcommittee's official business of the subcommittee in this, the new 103d Congress.

First, I would like to welcome my colleagues, some of whom are familiar faces around here and some of whom are new, to what I hope will be a very productive session for the subcommittee. Because if you look at our areas of jurisdiction we have a heck of a lot of work to do.

In bringing the hearing to order, I am reminded of an experience that befell Congressman Hancock of upstate New York. He was scheduled to speak at a political rally that opened with band music, and after the band played a couple of numbers the chairman

turned to the Congressman and said, do you want to speak now or shall we let them enjoy themselves a while more?

There is no band here, so I guess we will have to start.

Few issues affect people quite so profoundly as the issue of health care. But health care in America is in critical condition. Our commitment to provide every American with decent health care has been shaken in recent years by exploding costs that have already priced 35 million people in this country out of basic health insurance. More are added to their ranks each day. At nearly \$700 billion, health care spending consumed more than 12 percent of our GNP in 1991. By 1995, expenditures will exceed \$1 trillion, representing 15 percent of national output.

The diagnosis is in. Our national health care system is rife with waste and abuse, and it is time to put the patient in intensive care.

First and foremost, we must take a surgeon's scalpel to the most wasteful, inexcusable, and unconscionable cost of all, fraud. The cancer of fraud is depleting our already anemic health care system, and by all indications it is spreading into virtually every organ of the health care delivery system at a staggering rate.

The GAO estimates, for instance, that 10 percent of our total health care expenditures, public and private, are lost to fraud and abuse. That means we will lose a staggering \$80 billion to fraud this year alone. To put this hemorrhaging in perspective, our total Medicare outlays in 1991 amounted to \$110 billion. What we lose to fraud and abuse could pay for well more than half of the entire Medicare program which is one of the Federal Government's biggest expenditures.

If we stop payment on \$80 billion in fraud we could provide more than \$2,000 in health insurance for every American who currently has no coverage.

But, of course, more than dollars are at stake here. Health care fraud crimes are threatening the lives of millions of Americans, subjecting them to unnecessary treatment, false diagnosis, adulterated drugs, and causing them to forgo the treatments they might desperately need. In an incalculable number of cases, patients are placed in real danger so some con artist can make a fast buck. That is the true cost of health care fraud.

The scams these thieves use to victimize patients and their insurers are multiplying like bacteria on a July afternoon: Drug diversion schemes, kickback arrangements, telemarketing operations, rolling lab schemes, copayment waivers, prescription billing fraud. Each of these represents a huge category of health care fraud. In future weeks and months this subcommittee intends to explore as many of them as we can.

Against this avalanche of fraud the Federal Government stands ill-equipped, undermanned and overwhelmed. It is as if we sent out Barney Fife to meet the terminator.

To illustrate, the number of investigators in the Office of the Inspector General at HHS has stagnated in the past 5 years while the responsibilities of that Office, as well as the size and complexity of the Federal programs it oversees, have increased considerably. This means, for example, the IG has fewer than two full-time investigators devoted to health care fraud for all of southern California, one of the Nation's most populous regions.

Even though they have evidence of massive fraud being committed in our health care system, the lack of resources is forcing our law enforcement agents to subject cases to triage, whereby only the largest and most clear-cut cases are ever pursued. Hundreds, perhaps thousands of other cases that they already know about are not even investigated, let alone prosecuted.

The real casualty here, of course, is the health of our people. They are left virtually defenseless against latter day charlatans and snake oil salesmen that are out to profit from the illness, misfortune and insecurity of others.

The American people are clearly demanding change in our Nation's health care. We in Congress must not only work with our President to develop innovative, efficient ways to deliver health care, but we also must ferret out and terminate the fraud that is undermining the health and well-being of our citizens.

We will consider many ideas to accomplish this goal, including a national health care fraud data base to let Federal, State, and local agencies exchange information on fraud and abuse, intergovernmental task forces to allow law enforcement agencies to pool resources and jointly attack fraud, prohibition of kickbacks against private insurers, and ensuring integrity of electronic media by building fraud detection mechanisms into the processing system.

I plan to hold as many hearings as necessary to adequately consider the causes of this fraud and find responsible solutions to it.

Today we begin our examination of health care fraud. The doctor is in. When we are through with our diagnosis, it is our intent to fashion a legislative treatment to rid this wasteful malignancy from our Nation's health care system.

I thank my colleagues for their indulgence.

Now I call on Mr. Smith if he wishes to say something.

Mr. SMITH. Thank you, Mr. Chairman. I didn't know it was possible to use so many medical metaphors.

Mr. SCHUMER. It is easy.

Mr. SMITH. It paints a grim picture. Thank you for your leadership, and it is no surprise we are getting off to such a quick start this year. I look forward to the initiative you have shown, and I know that it will be very productive.

Seriously, there is a real interest in this subject matter today. We are talking about a subject that probably has touched the lives of millions of people in the United States in an adverse way, and we certainly need to move to correct the problems that we have. And I know the first individuals whom we will hear testify, Dr. Marr and Ms. Alderson—I read their testimony last night, and clearly these are examples that they are going to give us of complete, unmitigated health care fraud of the kind that this committee needs to address. I am glad we are going to do so.

I think we need to remind ourselves that the challenge to this committee is not just to hear how bad the problem is—I have a hunch we are going to prove that—but to move to find out what we can do in the way of changing Federal laws or better enforcing laws so as to try to help correct the problem.

Mr. Chairman, you mentioned something else earlier we are also familiar with and that is that health care fraud today totals something on the order of \$80 billion. I see that as having more rami-

fications than just the need to make sure that health care fraud is brought to a stop. I see that as having implications when it comes to reducing the deficit. Because if we do our jobs and if we do eliminate the fraud and abuse that exists in government today, whether in the health care area, could be defense, social services, could be in any number of areas, clearly we will have also helped the American economy and helped reduce the need and maybe even eliminated the need to ever talk about raising taxes.

First of all, we need to eliminate the fraud and abuse that exists in government.

Mr. Chairman, I have a quick question for you that you may be able to answer for us.

During the campaign—on the campaign trail, President Clinton, then Candidate Clinton, put out a campaign bible called Putting People First, and he made a number of promises to the American people on the general subject of crime and drugs. Among them, put 100,000 new police officers to work and expand community policing, that first-time nonviolent offenders serve out sentences in community boot camps, enact tough penalties for assaults against women and children to deter domestic violence, increase Federal funding for school-based and community drug education programs and treatment clinics, and provide Federal matching funds for crime prevention in hard-hit communities.

Mr. Chairman, have you heard from the President in regard to those specific subjects? And, if so, when can we expect proposed legislation from him in regard to those matters?

Mr. SCHUMER. I thank, Mr. Smith, and before I answer his question, I want to welcome him to the committee. I have worked with Mr. Smith, the gentleman from Texas, on the subject of immigration and many other issues. He is a conscientious, hard-working and decent-minded Member. I am glad he is now on the subcommittee.

Now, to answer your question—I wasn't going to just say that.

Mr. SMITH. That sounded good for a start.

Mr. SCHUMER. We have had some preliminary discussions with members of the transition team and the administration. I believe it is their intent to deal with every one of those issues that you mentioned.

As to when we will have a complete package, we don't have an answer for that yet. Obviously, the first focus of the administration is on the economy. However, they have assured me that crime and criminal justice is one of their highest priorities. They intend to devote a great deal of attention to it, and I expect we will be working closely with them to achieve those goals.

Mr. SMITH. Thank you, Mr. Chairman.

Mr. SCHUMER. Any other opening statement?

The gentleman from New Mexico who is just an outstanding member of this subcommittee, and I want to welcome him back since he was not in during the welcoming shift.

Mr. SCHIFF. Thank you, Mr. Chairman.

I can't resist adding to Mr. Smith's comments that in my State of New Mexico, a targeted State in the election—may not happen again with only five electoral votes, but it was by both sides—the Clinton campaign ran TV ads endorsing the death penalty. I hope

when you talk to the administration—I hope you see what plans they have for the death penalty.

With respect to this hearing, Mr. Chairman, I want to join Mr. Smith in offering my compliments to you for selecting this subject. There is a tendency for us working in crime and criminal law issues to focus on street crime which no one can doubt the importance of, but in terms of economic impact, which is another issue we have to look at, fraud has a tremendous effect even though, fortunately, people are not normally killed on the street through it. This should not understate the importance of this issue.

Particularly, the public is pressing the Congress to do something at the national level to lower the cost of medical care. Regardless of how we may agree or disagree on how exactly to approach the problem, we have that common goal. It is clear that no matter what we believe in terms of the ultimate philosophy we should adopt as a target for health care policy that fraud robs us all, takes away from the present system or any other system we may devise.

I would add a final thing. As the Chair knows, I was district attorney in the Albuquerque area for a number of years and assistant district attorney for a number of years before that. As district attorney, I supervised a statewide Medicaid provider fraud unit attached to my office, although this particular division had statewide responsibility.

What came out in the course of this unit's investigation is that, although the number of providers to the Government who conduct fraud is very small—quite to the contrary, many providers do health care for the poor and don't bother to bill the Government. They do it as part of their community and professional sense of responsibility—those few providers who do engage in fraud can cost the Government a fortune for the obvious reason.

The patient can only say I had so many teeth extracted or so many legs broken or so many babies. If a patient decides to engage in fraud, there is only a handful of things the individual can do to submit to the Government.

For the provider, there is no limit to the number of claims that can be submitted. In those few instances where a provider has decided to defraud the Government, the impact is astounding. One more reason why I appreciate you holding these hearings.

Thank you.

Mr. SCHUMER. We hope to use the gentleman's experience in crafting the legislation.

Mr. Gekas.

Mr. GEKAS. Thank you, Mr. Chairman.

Mr. SCHUMER. I want to welcome you back again. I am glad we have so many of our colleagues returning to the subcommittee and look forward to working with you in this and many other areas.

Mr. GEKAS. Thank you, Mr. Chairman.

On the very same day that we heard about the tragic airplane accident which took the life of Senator John Heinz 2 years ago, we also learned that he was on his way on that very flight to a conference that he had set up or a press conference in which he was to continue his investigative work in the very field in which this subcommittee is now undertaking. And we knew that he had made

some great discoveries and was well on his way to developing salutary legislation in this very field.

Soon after his death, some of us took up his work and produced a resolution and legislation to follow this issue through the Halls of Congress. This hearing today is in a continuum from that moment for those of us who became interested in that subject.

During the original period of consideration of this matter, following the death of Senator Heinz, with Senator Cohen and others we did hear the kinds of horror stories that have become commonplace now.

The one anecdote that fits the picture or casts the picture best in my judgment is the spectacle of a \$29 foam mattress that was ordered for an elderly patient, costing \$29. In Pennsylvania it was priced at \$293, and in New York it was priced at \$1,200. The same mattress from the same company in three different locations had this atrocious extremity of prices.

That is the example that we keep referring to trying to cast the proper abuse picture, that we will hear more from witnesses today. I am certain.

Following all of that, Senator Cohen and I and others began the legislation which will culminate in a total health care proposal for the Nation, and even my own modest proposal for health care reform includes certain provisions consolidating the administration of Medicare A and B, to join up those two facets of our health care system so that we could prevent duplication, reduce costs of administration, reduce waste, and reduce the possibility of claims of contractors and others going to several places at the same time; where we could bring possibly the end to that kind of purposeful double-billing and overlapping that sometimes causes some of the very waste about which we are gathered here today.

So not only do we have the vital issue before us but we have a history already built into the system to our own legislative mill that will be of greater assistance as we hear the witnesses and proceed on the issue.

Thank you, Mr. Chairman.

Mr. SCHUMER. Thank you, Mr. Gekas.

First, I think it is very appropriate that you mention the late Senator Heinz who did so much good work on this issue.

We have some examples which just graphically illustrate the problems that you spoke about.

This device is called a torso support. It was supposed to treat lower back pain. It is really simply a wheelchair restraint. Medicare paid \$200 for countless numbers of these—\$200. It costs \$7 to make.

That is one example.

This item is called a catheter care kit. It contains a device to help change a patient's catheter. It wholesales for \$2. Medicare paid \$30 each and lost \$3 million in claims.

There are so many.

This last one is a foot splint. It looks a little like Big Bird. The makers claim it would relieve foot drop. It couldn't. Had nothing to do with relieving foot drop. The wholesale value is \$65. Medicare was billed \$265.

Mr. GEKAS. I can use that in the gym.

Mr. SCHUMER. So there is a huge amount of fraud out there. This is just one area, durable medical equipment fraud. That is just one small part of the epidemic we are investigating.

Mr. GEKAS. If you would yield?

Mr. SCHUMER. I yield.

Mr. GEKAS. Since you mentioned durable medical equipment, it also must be said that while we are delving into this subject, that for the most part, the producers and distributors and marketers of the durable medical equipment are bona fide, good merchants of that needed commodity in this day and age. It is the very few, again, just like in every other circle of our society, very few among them who through telemarketing or some other devices are abusing the practice of marketing durable medical equipment.

I want the record to show eventually that this does not paint the brush so broadly as to include every single provider of durable medical equipment.

Mr. SCHUMER. Of course. Most of the providers are honest people, but fraud seeps its way in.

I want to welcome two more people, and then we will get to our panels.

First, our only freshman on the committee in a large and very outstanding freshman class. We want to welcome David Mann from Ohio. I look forward to his continued and active input in the committee.

Of course, I want to welcome my colleague Jim Sensenbrenner, our ranking member who has really done superb work. We have disagreed on some issues, agreed on others——

Mr. GEKAS. Some?

Mr. SCHUMER. Some. Not defining percentages. But we have worked together on many issues, and, throughout all of that, he has been a real asset, not just to this subcommittee but to the people of this country.

With that, let me also ask unanimous consent that an opening statement of another member of our panel who couldn't be here, Representative John Conyers, be added to the record. Without objection.

[The prepared statement of Mr. Conyers follows:]

PREPARED STATEMENT OF HON. JOHN CONYERS, JR., A
REPRESENTATIVE IN CONGRESS FROM THE STATE OF MICHIGAN

I congratulate the distinguished chairman of the Subcommittee for holding this important hearing today. Health care fraud is a growth industry and it must be stopped.

Recently the General Accounting Office prepared a report for the Subcommittee on Human Resources of the Government Operations Committee, which I chair, about health care fraud. Its findings were startling. The GAO estimated that there will be \$100 billion in fraud and abuse in the medical system by 1995. This report showed where we can get tens of billions of dollars each year to pay for the health care of average Americans, rather than to line the pockets of crooked doctors and greedy medical companies.

Health care providers have all sorts of sordid schemes to prey on the fears of the sick, and bilk the public and insurance companies out of vast sums of money. Phoney claims get filed, kickbacks get paid, fictitious visits are reported, drugs are billed for but never provided, tests get done that aren't needed, operations get performed that aren't warranted. And conflict of interest is rampant as doctors refer patients to labs they have a financial stake in.

Most of us don't trust our car mechanics -- it's one of those things in life like hating to visit the dentist. But we're talking about doctors, the people in whose hands we place our lives and those of our children. My friends, if you can't trust your doctor who can you trust.

To those doctors -- and I want to acknowledge that we are talking about a minority of doctors -- to those doctors who are engaged in this fraudulent and abusive activity I ask, whatever happened to your commitment to uphold the Hippocratic oath that guides your ethical and professional behavior? Does the Hippocratic oath say you should order tests when the patient doesn't need them, you should operate when the patient is well, and you should charge the payers when you haven't offered any service?

The question before us is how do we end this massive corporate and physician rip-off. And this goes to the heart of the debate on which type of national health care reform makes the most sense. There are several major obstacles to preventing and detecting fraud and abuse. They include:

- The many and complicated claims data systems maintained by over 1,200 insurance companies, Medicaid and Medicare with their different exclusions and payment requirements;
- The difficulty in identifying corrupt provider billing patterns because there are so many different payers;
- The privacy concerns of sharing data between the government and private insurers;
- The lack of public control over physicians and medical companies that invest in technology whether it's needed or not, because they have the power to prescribe it to their patients.

I would maintain that many of these problems could best be controlled under a national health insurance system, where each state government acted as the single-payer to health care providers. Paperwork would be simplified and drastically reduced, doctors who billed more than 12-14 hours of visits on a single day could be easily caught, physicians who had practice patterns outside the norm could be easily identified, and "rolling labs" would need permission to operate from the local government.

Now there are two good reasons for the Congress to pass a single-payer national health insurance program: the \$67 billion GAO estimated could be saved in paperwork (in a report prepared for the Government Operations Committee) if a single-payer health insurance system were adopted in the U.S., and the tens of billions that could be saved in reduced fraud and abuse. Shortly I, along with the distinguished chairman of this Subcommittee, Mr. McDermott of Ways and Means, and other members will introduce such a proposal in the House.

Finally, I'd like to thank Mr. Larry Potts, Assistant Director at the FBI and one of our witnesses today, for briefings he has provided to my staff with regard to a health care fraud investigation in Michigan. I'd also like to acknowledge the excellent work on health care matters provided by the GAO under the direction of Ms. Janet Shikles.

Again, I commend the Subcommittee chairman for having this important hearing and look forward to hearing from today's witnesses.

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Mr. SCHUMER. Now we will ask the first panel to come forward, Dr. Marr and Ms. Alderson.

Our first panel this morning is comprised of two victims of health care fraud, Dr. William Marr and Susan Alderson.

Dr. Marr is a distinguished member of the medical community, as well as an insurance company executive. He has practiced medicine in various capacities since 1959 and is currently vice president and senior medical director of the Mutual of Omaha Insurance Co. While he is well-versed on health care fraud from a professional standpoint, he and his wife became victims of a massive health care scam in 1987 while living in California.

Susan Alderson is a former psychiatric patient from a hospital near Dallas, TX. Although she expected her treatment to last for a few days, she was confined for 3 months, a victim of a particularly heinous form of fraud which she will tell us about. She has testified before the Texas Legislature which, along with the Texas Attorney General's Office, launched a widespread investigation into psychiatric health care fraud. Many of the hospitals in question have since closed down as part of an out of court settlement.

I want to thank each of you for being here. Your prepared statements will be entered in the record.

We will begin with Dr. Marr and Ms. Alderson.

STATEMENT OF WILLIAM L. MARR, M.D., VICE PRESIDENT AND SENIOR MEDICAL DIRECTOR, CLAIMS, MUTUAL OF OMAHA

Dr. MARR. Good morning, I want to thank the chairman for asking me to testify before the Crime and Criminal Justice Subcommittee.

My name is William Marr, and I am a medical doctor by training and profession. I have been medical director of three large insurance companies since 1974.

While I was employed as medical director for Pacific Mutual Life in California, I began to see claims referred to me for services that fit into a similar pattern. Our insured would be billed for multiple lab type procedures by several providers on the same date of service with total charges of several thousand dollars. Often these providers were billing from different addresses in different cities. Various diagnoses were provided on the claim forms to justify medical necessity.

On investigating these claims, our insureds related that they had been solicited by telemarketing methods and that they had been told that the clinics would accept insurance payment as payment in full.

Ironically, on July 6, 1987, I received a telephone call at home from a Mr. Simon Barker of the Southcoast Cardiopulmonary Center in Santa Ana. He invited me and my wife to undergo a complete physical by one of their doctors, who was AMA approved. He indicated there would be no charge as a waiver would be signed releasing me from any deductible, copayment or balance billing.

I discussed this solicitation with my company and contacted Ken Kensler, criminal investigator of the Department of Insurance, Fraud Bureau, State of California. Our benefit office had been providing claim information to that department on similar claims.

On July 14, 1987, my wife and I began our appointment at Southcoast Cardiopulmonary Medical Center. We were asked to complete several forms. A waiver was signed by them that I would have no responsibility for the charges. A medical questionnaire was completed and xerox copy of my insurance card was made. They told us of the various tests which would be performed on us. Tests were then done—pulmonary function, electrocardiogram—and urine and blood specimens were taken.

Next, Dr. Richard Hiler reviewed my health question form and asked some additional questions. Another man was in the room, who Dr. Hiler identified as a medical student.

I related that I had been told my cholesterol and triglycerides had been elevated in the past. Dr. Hiler told the other man that he would put that information up front because the insurance company liked to see that. I believe that this reference was made because they believe the insurer could be misled into paying for the entire test series if they referenced the information regarding my elevated cholesterol and triglycerides.

He then did a physical exam on me while I was still dressed. I was then taken to another room where an echocardiogram and ultrasound of my abdominal organs were done by Winston Spell. That was followed by Doppler studies of my extremities and major arteries by the technicians referred to as Danny and Lucky. Mr. Spell told me I have one or two things enlarged in my heart.

I want to note that most of these tests were not medically necessary in the absence of complaints or positive physical findings, and I can assure you that I did not have enlargement of my heart.

We were then given an appointment to go to their Tustin office on July 21, 1987, for additional testing. We arrived, as appointed, on July 21 at Fitness Spectrum. Again, we were assured we would not be billed. We visited with a nutritionist, a chiropractor and then I had a cardiac output test. I was then taken to a room for a cardiac exercise stress test. I saw no resuscitation equipment in the room as is standard procedure. Next I had muscle testing.

We returned to Fitness Spectrum on August 19, 1987, and I was told I had some narrowing of my right carotid and femoral arteries; and that I had enlargement of the right side of my heart, and mild pulmonary fibrosis.

The bills for these services began to arrive July 31, 1987. My wife and I were billed approximately \$7,500 each. The bills included the unjustified diagnoses. Also, service coding abuse was present, unbundling and use of complex service codes.

Pacific Mutual rejected these claims as benefits are not provided for services for which one is not obligated to pay. Rebilling continued by various named facilities until December 1990, some 2½ years after the initial testing.

On October 29, 1987, a few months after our original experience with South Coast Cardiopulmonary and Fitness Spectrum, I was resolicited by telephone to take part in an early detection program at Meta-Life Cardiomedical Center. Various tests would be done, and Meta-Life would bill my insurance company as payment in full. This was the same location as Fitness Spectrum in Tustin, where I had previously been.

If you can believe this, 3 years later I received a third solicitation from the Santa Ana Medical Center.

The subcommittee may want to know how an operation such as this affects the community. These schemes not only increase the costs of an already overburdened health care system but they have a potential detrimental impact on victims targeted. Various inappropriate diagnoses affixed to the claim form may become part of the person's insurance record and new or additional coverage may be adversely influenced by these health impairments. Patients or consumers are needlessly frightened of false diagnoses of health problems.

Additional expense is generated by the concerned participant because they now take these reports to their regular attending physician, who may repeat studies or order additional evaluations in an effort to prove the presence or absence of these impairments that have been diagnosed.

The cost of fraudulent claims ultimately may be passed along to consumers. Consumers solicited to go through the operation may still be out of pocket some money as some cash payment was requested up front to show good faith.

Mr. Chairman and members of the subcommittee, thank you for inviting me to testify today, and I will be happy to answer any questions the subcommittee may have on this important issue.

Mr. SCHUMER. Thank you, Dr. Marr.

[The prepared statement of Dr. Marr follows:]

PREPARED STATEMENT OF WILLIAM L. MARR, M.D., VICE PRESIDENT
AND SENIOR MEDICAL DIRECTOR, CLAIMS, MUTUAL OF OMAHA

GOOD MORNING.

I WOULD LIKE TO THANK THE CHAIRMAN FOR ASKING ME TO TESTIFY BEFORE THE CRIME AND CRIMINAL JUSTICE SUBCOMMITTEE TODAY TO SHARE WITH YOU MY PERSONAL EXPERIENCE WITH THE ROLLING LABS IN SANTA ANA AND TUSTIN, CALIFORNIA. I WILL SUMMARIZE MY REMARKS BUT WOULD LIKE TO REQUEST THAT MY FULL WRITTEN STATEMENT BE INCLUDED IN THE RECORD.

MY NAME IS WILLIAM MARR. I AM A MEDICAL DOCTOR BY TRAINING AND PROFESSION. I DID MY SPECIALTY WORK IN INTERNAL MEDICINE AND WAS IN PRIVATE PRACTICE IN GALVESTON, TEXAS, FOR 16 YEARS. I HAVE ALSO BEEN MEDICAL DIRECTOR FOR THREE LARGE INSURANCE COMPANIES SINCE 1974. WHILE EMPLOYED AS VICE PRESIDENT AND MEDICAL DIRECTOR FOR PACIFIC MUTUAL LIFE INSURANCE COMPANY IN NEWPORT BEACH, CALIFORNIA, FROM 1982 TO 1989, MY PRIMARY RESPONSIBILITY WAS FOCUSED ON HEALTH INSURANCE REIMBURSEMENT ISSUES. IN ABOUT 1985, I BEGAN TO SEE CLAIMS REFERRED TO ME FOR SERVICES THAT FIT INTO A SIMILAR PATTERN. OUR INSURED WOULD BE BILLED FOR MULTIPLE LAB-TYPE PROCEDURES BY SEVERAL PROVIDERS ON THE SAME DATE OF SERVICE, WITH TOTAL CHARGES OF SEVERAL THOUSAND DOLLARS. OFTEN THESE PROVIDERS WERE BILLING FROM DIFFERENT ADDRESSES IN DIFFERENT CITIES. VARIOUS DIAGNOSES WERE PROVIDED ON THE CLAIM FORMS TO JUSTIFY MEDICAL NECESSITY. ON INVESTIGATING THESE CLAIMS, OUR INSURED RELATED THAT THEY HAD BEEN SOLICITED BY TELEMARKETING METHODS AND THAT THEY HAD BEEN

TOLD THAT THE CLINICS WOULD ACCEPT INSURANCE PAYMENT AS PAYMENT IN FULL.

IRONICALLY, ON JULY 6, 1987, I RECEIVED A TELEPHONE CALL AT HOME FROM A MR. SIMON BARKER OF THE SOUTHCOAST CARDIOPULMONARY CENTER IN SANTA ANA. HE INVITED ME (AND MY WIFE) TO UNDERGO A COMPLETE PHYSICAL BY ONE OF THEIR DOCTORS, "WHO WAS AMA APPROVED." WE WOULD RECEIVE A BLOOD CHEMISTRY PANEL TESTING 36 ITEMS, NUTRITIONAL ANALYSIS, ALLERGY TESTING, ULTRASOUND STUDIES OF THE HEART, LIVER, KIDNEYS AND SPLEEN. ALSO, DOPPLER STUDIES OF THE BLOOD VESSELS AND PULMONARY STUDIES. HE INDICATED THERE WOULD BE NO CHARGE AS A WAIVER WOULD BE SIGNED RELEASING ME FROM ANY DEDUCTIBLE, CO-PAYMENT OR BALANCE BILLING. HE ASKED IF I SMOKED, AND I REPLIED, "NO" . . . HE SAID "THAT'S GOOD" BUT THE AIR HERE IS SO POLLUTED, IT'S GOOD TO HAVE THESE TESTS.

I DISCUSSED THIS SOLICITATION WITH MY COMPANY AND CONTACTED KEN KENSLE, CLINICAL INVESTIGATOR OF THE DEPARTMENT OF INSURANCE, FRAUD BUREAU, FOR THE STATE OF CALIFORNIA. OUR CLAIM AREA HAD BEEN PROVIDING CLAIM INFORMATION TO THAT DEPARTMENT ON SIMILAR CLAIMS. ON JULY 10, 1987, I RECEIVED A TELEPHONE CALL FROM "SANDRA," WHO SET UP AN APPOINTMENT FOR OUR VISIT.

ON JULY 14, 1987, MY WIFE AND I BEGAN OUR APPOINTMENT AT SOUTHCOAST CARDIOPULMONARY MEDICAL CENTER. WE WERE ASKED TO COMPLETE A FORM PROVIDING OUR NAME, ADDRESS, SEX, AGE, SOCIAL SECURITY NUMBER, INSURANCE DETAILS, PAST MEDICAL HISTORY AND

FAMILY HISTORY. A WAIVER WAS SIGNED BY THEM THAT I WOULD HAVE NO RESPONSIBILITY FOR THE CHARGES. A MEDICAL QUESTIONNAIRE WAS COMPLETED AND XEROX COPY OF MY INSURANCE CARD WAS MADE. "RAY" TOLD US OF THE VARIOUS TESTS WHICH WOULD BE PERFORMED ON US. TESTS WERE THEN DONE (PULMONARY FUNCTION, ELECTROCARDIOGRAM) AND URINE AND BLOOD SPECIMENS WERE TAKEN. NEXT, DR. RICHARD HILER REVIEWED MY HEALTH QUESTION FORM AND ASKED SOME ADDITIONAL QUESTIONS. ANOTHER MAN WAS IN THE ROOM, WHO DR. HILER IDENTIFIED AS A MEDICAL STUDENT. I RELATED THAT I HAD BEEN TOLD MY CHOLESTEROL AND TRIGLYCERIDES HAD BEEN ELEVATED IN THE PAST. DR. HILER TOLD THE OTHER MAN THAT HE WOULD PUT THAT INFORMATION UP FRONT BECAUSE THE INSURANCE COMPANY LIKED TO SEE THAT. HE TOLD THE MAN THAT HE WAS DOING SEVERAL THOUSAND DOLLARS OF TESTING, AND THE CARRIER WILL PAY MORE IF HE PUT THAT UP FRONT . . . "THEY WILL PAY ANYWAY, BUT WILL PAY MORE WITH THIS". I BELIEVE THAT THIS REFERENCE WAS MADE BECAUSE THEY BELIEVE THE INSURER COULD BE MISLEAD INTO PAYING FOR THE ENTIRE TEST SERIES IF THEY REFERENCED THE INFORMATION REGARDING MY ELEVATED CHOLESTEROL AND TRIGLYCERIDES. HE THEN DID A PHYSICAL EXAM ON ME WHILE I WAS STILL DRESSED (AND CHARGED \$295 FOR THE PHYSICAL). I WAS THEN TAKEN TO ANOTHER ROOM WHERE AN ECHOCARDIOGRAM AND ULTRASOUND OF MY ABDOMINAL ORGANS WERE DONE BY WINSTON SPELL. THAT WAS FOLLOWED BY DOPPLER STUDIES OF MY EXTREMITIES AND MAJOR ARTERIES BY THE TECHNICIANS REFERRED TO AS "DANNY" AND "LUCKY". MR. SPELL

TOLD ME I HAVE ONE OR TWO THINGS ENLARGED IN MY HEART. I WANT TO NOTE THAT MOST OF THESE TESTS WERE NOT MEDICALLY NECESSARY IN THE ABSENCE OF COMPLAINTS OR POSITIVE PHYSICAL FINDINGS AND I CAN ASSURE YOU THAT I DID NOT HAVE ENLARGEMENT OF MY HEART.

WE WERE THEN GIVEN AN APPOINTMENT TO GO TO THEIR TUSTIN OFFICE ON JULY 21, 1987, FOR ADDITIONAL TESTING. WE ARRIVED, AS APPOINTED, ON JULY 21 AT FITNESS SPECTRUM IN TUSTIN, CALIFORNIA. AGAIN, WE WERE ASSURED WE WOULD NOT BE BILLED. WE VISITED WITH A NUTRITIONIST WHO SAID I HAD NO LIVER OR KIDNEY DISEASE OR LEUKEMIA (REFERRING TO MY RECORD). A CHIROPRACTOR, DR. LEREUSE, EXAMINED ME FOR MUSCULOSKELETAL DISEASE. DR. BRUCE SEVILLE ASKED ME SEVERAL QUESTIONS, AND THEN I HAD A CARDIAC OUTPUT TEST. I WAS THEN TAKEN TO A ROOM FOR A CARDIAC EXERCISE STRESS TEST. I SAW NO RESUSCITATION EQUIPMENT IN THE ROOM AS IS STANDARD PROCEDURE. NEXT I HAD MUSCLE TESTING.

WE RETURNED TO FITNESS SPECTRUM ON AUGUST 19, 1987, AND SAW DR. MYUNG HA SOHN FOR VERBAL REPORTS. HE SAID I HAD SOME NARROWING OF MY RIGHT CAROTID AND FEMORAL ARTERIES. I HAD ENLARGEMENT OF THE RIGHT SIDE OF MY HEART AND MILD PULMONARY FIBROSIS. FORMS WERE COMPLETED FOR THE CLINIC TO MAIL MY REPORTS TO ME.

EVEN BEFORE WE RETURNED TO FITNESS SPECTRUM, ON JULY 30, 1987, I RECEIVED A LETTER FROM THE CARDIOPULMONARY MEDICAL CENTER REGARDING THEIR SCREENING CHARGES. THEY STATED, "THE GROSS

CHARGES ON OUR BILLS TO INSURANCE COMPANIES ARE MUCH HIGHER THAN THE USUAL CHARGES BECAUSE OUR REIMBURSEMENT FOR ALL THE TESTS DONE IN OUR MEDICAL CENTER PER MONTH AVERAGES ONLY 6%-7% OF THE GROSS CHARGES. IT IS ALSO IMPORTANT TO NOTE THAT, AS A RULE, INSURANCE COMPANIES ALLOW LESS THAN WHAT A PROVIDER WILL CHARGE." IT WOULD APPEAR THAT THIS STATEMENT WAS SUBMITTED TO THEIR PATIENTS TO, IN SOME WAY, NEUTRALIZE THE IMPACT OF THESE EXCESSIVE CHARGES.

THE BILLS FOR THESE SERVICES BEGAN TO ARRIVE JULY 31, 1987. MY WIFE AND I WERE BILLED APPROXIMATELY \$7,500 EACH. THE BILLS INCLUDED THE UNJUSTIFIED DIAGNOSES. ALSO, SERVICE CODING ABUSE WAS PRESENT, UNBUNDLING AND USE OF COMPLEX SERVICE CODES. AN EXAMPLE IS THE INITIAL EXAM ON JULY 14, 1987, WITH A CHARGE OF \$295 FOR 90020 . . . COMPREHENSIVE PHYSICAL EXAM. ANOTHER EXAMPLE IS THE UNBUNDLED BLOOD CHEMISTRY PANEL CHARGE OF \$747 FOR A STUDY THAT COSTS APPROXIMATELY \$24 IN A RECOGNIZED REFERENCE LAB.

PACIFIC MUTUAL REJECTED THESE CLAIMS AS BENEFITS ARE NOT PROVIDED FOR SERVICES FOR WHICH ONE IS NOT OBLIGATED TO PAY. REBILLING CONTINUED BY VARIOUS NAMED FACILITIES UNTIL DECEMBER 1990. . . SOME TWO AND A HALF YEARS AFTER THE INITIAL TESTING.

ON OCTOBER 29, 1987, A FEW MONTHS AFTER OUR FIRST EXPERIENCE WITH SOUTH COAST CARDIOPULMONARY AND FITNESS SPECTRUM, I WAS RESOLICITED BY TELEPHONE TO TAKE PART IN AN "EARLY DETECTION

PROGRAM" AT META-LIFE CARDIOMEDICAL CENTER. VARIOUS TESTS WOULD BE DONE AND META-LIFE WOULD BILL MY INSURANCE COMPANY AS PAYMENT IN FULL. THIS WAS THE SAME LOCATION AS FITNESS SPECTRUM IN TUSTIN, WHERE I HAD PREVIOUSLY BEEN.

ON MARCH 31, 1989, I RECEIVED A THIRD SOLICITATION FROM MR. KEN KENT OF THE SANTA ANA MEDICAL CENTER, "INTRODUCING OUR MEDICAL CENTER TO THE PEOPLE OF IRVINE WHO HAVE INSURANCE." "WE ENCOURAGE YOU TO TAKE YOUR REPORTS TO YOUR DOCTOR. WE ARE PRIMARILY INTERESTED IN SAVING LIVES. PETE MARAVICH, A PROFESSIONAL BASKETBALL PLAYER, DROPPED DEAD DESPITE REPEATED PHYSICALS. WE PICKED UP A WOMAN WITH CANCER OF THE CERVIX AND SAVED HER. WE NEED REGULAR CHECK-UPS JUST LIKE OUR CARS." HE SAID THEY HAVE DONE NUMEROUS EXAMS FOR MY INSURANCE CARRIER AND HAVE HAD NO PROBLEM WITH PAYMENT. "MOST INSURANCE COMPANIES FEEL THEY WANT HEALTHY CLIENTS AND THAT MINOR PROBLEMS CAUGHT EARLY ARE EASILY TREATED AVOIDING EXPENSIVE HOSPITALIZATION."

HOW DOES AN OPERATION SUCH AS THIS AFFECT THE COMMUNITY?

1. MR. CHAIRMAN, THESE SCHEMES NOT ONLY INCREASE THE COSTS TO OUR ALREADY OVERBURDENED HEALTH CARE SYSTEM, BUT THEY ALSO HAVE A POTENTIAL DETRIMENTAL IMPACT ON THE VICTIMS THAT THEY TARGET.
2. VARIOUS INAPPROPRIATE DIAGNOSES AFFIXED TO THE CLAIM FORMS MAY BECOME PART OF THE PERSON'S INSURANCE RECORD AND NEW OR

ADDITIONAL COVERAGE MAY BE ADVERSELY INFLUENCED BY THESE
"HEALTH IMPAIRMENTS."

3. PATIENTS OR CONSUMERS ARE NEEDLESSLY FRIGHTENED OF FALSE
DIAGNOSES OF HEALTH PROBLEMS.
4. ADDITIONAL EXPENSE IS GENERATED BY THE CONCERNED PARTICIPANT
BECAUSE THEY NOW TAKE THESE REPORTS TO THEIR REGULAR
ATTENDING PHYSICIAN, WHO MAY REPEAT STUDIES OR ORDER
ADDITIONAL EVALUATIONS IN AN EFFORT TO PROVE THE PRESENCE OF
THESE IMPAIRMENTS THAT HAVE BEEN "DIAGNOSED."
5. THE COST OF FRAUDULENT CLAIMS ULTIMATELY MAY BE PASSED ALONG
TO CONSUMERS.
6. CONSUMERS SOLICITED TO GO THROUGH THE OPERATION MAY STILL BE
OUT OF POCKET SOME MONEY AS SOME CASH PAYMENT WAS REQUESTED
UP FRONT "TO SHOW GOOD FAITH."

MR. CHAIRMAN, THANK YOU FOR INVITING ME TO TESTIFY TODAY,
AND I WILL BE HAPPY TO ANSWER ANY QUESTIONS THE SUBCOMMITTEE MAY
HAVE ON THIS IMPORTANT ISSUE.

Mr. SCHUMER. Ms. Alderson.

STATEMENT OF SUSAN ALDERSON, CARROLLTON, TX

Ms. ALDERSON. Good morning. My name is Susan Alderson, and I reside in Carrollton, TX, which is a suburb of Dallas.

I am a victim of what you might call too good insurance. I will explain. I entered Brookhaven Psychiatric Hospital on June 26, 1987, and was kept there against my will until September 24, 1987. I entered the hospital voluntarily upon my company doctor's recommendation and only expected to be there a few days.

I was having a psychotic reaction to the pain medication Percodan. I have Crohn's disease and after numerous surgeries had been prescribed Percodan by my doctor. This was the first time I had ever had this type of reaction. I do have a low tolerance to many medications as a result of my disease, and I was also under a lot of job stress at the time. The two obviously do not mix.

I was entered into the hospital for drug addiction, not reaction, but sometime during the first week this classification was changed to alcoholism. I now know that this was done so they could keep me in there. They had obviously checked my insurance and found I was worth \$50,000 under my company policy.

I learned about the alcoholic diagnosis from another patient. In fact, I learned a lot from the other patients and confirmed information with some of the nurses.

My first night in the hospital I suffered a cardiac arrest when they tried to put me in restraints. I knew something had happened but didn't learn the extent of it until 7 or 8 weeks later when I was told by another patient. Nothing was ever told to me by the doctor or nurses, but what the doctor told my daughter the next day was that I had had a minor medical emergency.

In the meantime, after a few days in the hospital, my family was told I was a drug addict and was suicidal and a danger to myself and to them. Never was alcoholism mentioned to them by the doctor. I was the one who told them about the alcoholism months later, and they were stupefied. They know that because of my disease I had hardly touched liquor in over 10 years. They refuted this to the doctor, but no one would listen to them.

During the first 4 to 6 weeks I was kept heavily sedated and remember things in bits and pieces. I do know that if I tried to make waves they threatened me by saying they would take me to court and have me committed to a mental hospital for the rest of my life. I didn't know they couldn't do this without my family's approval. Also, other things happened to other patients that were degrading and humiliating and made me not want to make waves. I decided to behave myself and play their game until I could have contact with my family.

I did find out that the other patients were there because of different monetary factors. A lot were there because of good coverage by workers compensation benefits. This is what I was there under.

Others were there because of good company insurance. That is what I fell under. Others had family money. And then there were the 30-day wonders, as they were dubbed by the other patients. The 30-day wonders were people whose insurance had a 30-day

stay for mental problems. It was amazing how they were miraculously cured at the end of their 30-day stay.

Many of the other patients talked of the insurance and money factor during the time I was there, but every time I broached the subject about the insurance the doctor, nurses and therapists were always evasive. They said things like, I needn't worry about it, to, it wasn't any of my business.

Then, during about my seventh week, I was told by my doctor that they were working on getting me reclassified with the insurance company from major mental to major medical. The doctor said this during a meeting and in front of other patients. I asked what they meant, and he said it meant I—meaning my insurance—would go from being worth \$50,000 to a million dollars. I was stunned and felt that meant I could be kept there indefinitely. I didn't say anything because I knew I needed to get this information to my family.

The doctor mentioned this on several occasions. He also told me that by going from mental to medical I would be covered 100 percent rather than 80 percent. The doctor and hospital tried twice to reclassify me but were turned down both times. This took place over a period of 6 weeks during which time several unnecessary tests were run by a cardiologist and neurologist. The doctor then told me my Crohn's disease had spread. My personal doctor has since confirmed that it had not.

As I mentioned earlier, I was not allowed any communication with my family for almost 8 weeks. When I did see them, we were monitored by a psychotherapist, so I had to be careful how I passed information on to them.

One of my daughters was working for a law office during this time, and she had consulted with some of the attorneys about what was going on—in other words, no visitation rights, that my family could not take me out and about the doctor trying to reclassify my diagnosis.

One attorney phoned the hospital to speak with the doctor. He was quickly cut short, and all other attempts to contact the doctor were rebuffed. One of the nurses told me they were instructed not to talk to anyone, family included, about me.

Discussion had been going on in the family on whether to let me stay in the hospital or not. The doctor was telling them one thing, and I was telling them another.

One thing that had been pointed out by the doctor was that the insurance was about to run out and any additional days stayed in the hospital the family would be responsible for payment. The family knew I was upset and scared and finally on the night of December 24 my daughter came up to the hospital and literally beat on the doors and told them to release me or she was going to call the police. After getting the doctor up there the nurses told me to pack my things, and I was escorted out without being able to even say goodbye to the other patients.

After attending the hearings in Arlington, TX, I feel that the doctor who sent me to Brookhaven may have been one of the bounty hunters paid by PIA—Psychiatric Institutes of America—for sending them patients. I feel this because there were two other psychiatric facilities closer to my office. In fact, one was only 5 min-

utes away. I went voluntarily thinking I would be there for just a few days as my company doctor had told me—not 3 months.

Also, after seeing the charges on the few medical bills I was able to obtain, I feel there were overcharges on medication received, especially imodium and desyrel, maintenance drugs for my Crohn's disease. For example, I was charged anywhere from \$11 to \$46 per day for imodium, even though the dosage was always exactly the same. The same drug I purchase at my local pharmacy at only a fraction of what the hospital billed me.

I also question whether I was even given some of the drugs listed on the bills. The doctor's bills were also controversial because I was billed for his group therapies that he did not even attend sometimes. Sometimes the therapy was led by one of two other doctors, nurses or therapy students. I only saw the doctor four or five times on a one-on-one basis.

I have been unable to get detailed copies of my bills either from the doctors, hospital or insurance company. I do know my insurance paid \$48,863.92 toward hospital and doctor bills which was 80 percent coverage. A few more days and I would have reached my insurance worth of \$50,000. I still received bills from the doctors and hospital amounting to over \$10,000. That is what the 80 percent didn't cover according to them.

Those 3 months in Brookhaven have caused me much mental anguish. I cannot handle stress well now. I visited a psychologist after I got out of the hospital, but I stopped going after a few sessions because I feared that if I said something wrong I would be recommitted. The psychologist was still working with Brookhaven. I know my family would never let that happen, but the fear is still there.

I am here today in the hopes that what happened to me will not happen to anyone else and, also, that the fraudulent actions by PIA will be stopped. They are one of the reasons health care is so expensive today. This must stop.

I would like to add something.

Mr. SCHUMER. Please.

Ms. ALDERSON. PIA was owned by NME. That area has been absorbed by NME. I believe it goes under another name now, but I don't know what it is. Also they have only about one hospital left in Texas operating.

Mr. SCHUMER. Thank you, Ms. Alderson. Do you know the name for the acronym you gave us?

Ms. ALDERSON. National Medical Enterprises.

Mr. SCHUMER. You say they are the ones who have one hospital left?

Ms. ALDERSON. If they had absorbed PIA, yes.

[The prepared statement of Ms. Alderson follows:]

PREPARED STATEMENT OF SUSAN ALDERSON, CARROLLTON, TX

COMMITTEE MEMBERS

My name is Susan Alderson and I reside in Carrollton, Texas which is a suburb of Dallas.

I am a victim of what you might call "Too Good Insurance." I will explain, I entered Brockhaven Psychiatric Hospital on 26 June 1987 and was kept there against my will until 24 September 1987. I entered the hospital voluntarily upon my company doctor's recommendation, and only expected to be there a few days. I was having a psychotic reaction to the pain medication percodan. I have Crohn's Disease and after numerous surgeries had been prescribed percodan by my doctor. This was the first time I had ever had this type of reaction. I do have a low tolerance to many medications as a result of my disease, and I was also under a lot of job stress at the time. The two obviously do not mix.

I was entered into the hospital for drug addiction, not reaction, but sometime during the first week this classification was changed to alcoholism. I now know that this was done so they could keep me in there. They had obviously checked my insurance and found I was worth \$50,000 under my company policy.

I learned about the "alcoholic" diagnosis from another patient. In fact I learned a lot from the other patients and confirmed information with some of the nurses. My first night in the hospital I suffered a cardiac arrest when they tried to put me in restraints. I knew something had happened but didn't learn the extent of it until seven or eight weeks later when I was told by another patient. Nothing was ever told to me by the doctor or nurses, but what the doctor told my daughter the next day was that I had had a minor medical emergency.

In the meantime, after a few days in the hospital, my family was told I was a drug addict and was suicidal and a danger to myself and them. Never was alcoholism mentioned to them by the doctor. I was the one who told them about the "alcoholism" months later and they were stupefied. They know that because of my disease I had hardly touched liquor in over 10 years. They refuted this to the doctor, but no one would listen to them.

During the first 4 to 6 weeks I was kept heavily sedated and remember things in bits and pieces. I do know that if I tried to "make waves" they threatened me by saying they would take me to court and have me committed to a mental hospital for the rest of my life. I didn't know they couldn't do this without my families approval. Also other things happened to other patients that were degrading and humiliating and made me not want to make waves. I decided to behave myself and play their game until I could have contact with my family.

I did find out that the other patients were there because of different monetary factors. A lot were there because of good coverage by workers compensation benefits. Others were there because of good company insurance. That is what I fell under. Others had family money. And then there were the "30 Day Wonders" as they were dubbed by the other patients. "30 Day Wonders" were people whose insurance had a 30 day stay for mental problems. It was amazing how they were "miraculously" cured at the end of their 30 day stay.

Many of the other patients talked of the insurance and money factor during the time I was there, but every time I broached the subject about my insurance the doctor, nurses, and therapists were always evasive. They said things like "I needn't worry about it" to "It wasn't any of my business." Then during about my seventh week I was told by my doctor that they were working on getting me reclassified with the insurance company from major mental to major medical. The doctor said this during a meeting and in front of other patients. I asked what that meant, and he said it meant I (meaning my insurance) would go from being worth \$50,000 to a million dollars. I was stunned, and felt that meant I could be kept there indefinitely. I didn't say anything because I knew I needed to get this information to my family. The doctor mentioned this on several occasions. He also told me that by going from mental to medical I would be covered 100% rather than 80%. The doctor and hospital tried twice to reclassify me, but were turned down both times. This took place over a period of 6 weeks during

which time several unnecessary tests were run by a gastroenterologist and neurologist. The doctor then told me my crohn's disease had spread. My personal doctor has since confirmed that it had not.

As I mentioned earlier I was not allowed any communication with my family for almost 8 weeks. When I did see them we were monitored by a psycho-therapist so I had to be careful of how I passed information on to them. One of my daughters was working for a law office during this time and she had consulted with some of the attorney's about what was going on - ie. no visitation rights, that my family could not take me out, and about the doctor trying to reclassify my diagnosis. One attorney phoned the hospital to speak with the doctor, he was quickly cut short and all other attempts to contact the doctor were rebuffed. One of the nurses told me they were instructed not to talk to anyone, family included, about me. Discussion had been going on in the family on whether to let me stay in the hospital or not, the doctor was telling them one thing and I was telling them another. One thing that had been pointed out by the doctor was that the insurance was about to run out and any additional days stayed in the hospital the family would be responsible to pay. The family knew I was upset and scared and finally on the night of 24 September my daughter came up to the hospital and literally beat on the doors and told them to release me or she was going to call the police. After getting the doctor up there the nurses told me to pack my things and I was "escorted" out without being able to even say goodbye to the other patients.

IN SUMMATION:

After attending the hearings in Arlington, Texas I feel that the doctor who sent me to Brookhaven may have been one of the "bounty hunters" paid by PIA (Psychiatric Institutes of America) for sending them patients. I feel this because there were 2 other psychiatric facilities closer to my office - in fact one was only 5 minutes away. I went voluntarily thinking I would be there for just a few days as my company doctor had told me - not 3 months.

Also after seeing the charges on the few medical bills I was able to obtain, I feel there were overcharges on medication received, especially imodium and desyrel, maintenance drugs for my crohn's disease. For example, I was charged anywhere from \$11 to \$46 per day for imodium even though the dosage was always exactly the same. The same drug I purchase at my local pharmacy at only a fraction of what the hospital billed me. I also question whether I was even given some of the drugs listed on the bills. The doctors bills were also controversial, because I was billed for his group therapies that he did not even attend sometimes. Sometimes the therapy was led by one of two other doctors, nurses, or therapy students. I only saw the doctor 4 or 5 times on a one-on-one basis. I have been unable to get detailed copies of my bills either from the doctors, hospital, or insurance company.

I do know my insurance paid \$48,863.92 towards hospital and doctor bills which was 80% coverage. A few more days and I would have reached my insurance worth of \$50,000. I still received bills from the doctors and hospital amounting to over \$10,000.

Those three months in Brookhaven have caused me much mental anguish. I can not handle stress well now. I visited a psychologist after I got out of the hospital, but I stopped going after a few sessions, because I feared that if I said something wrong I could be committed. The psychologist was still working with Brookhaven. I know my family would never let that happen but the fear is still there. I am here today in the hopes that what happened to me will not happen to anyone else. And also that the fraudulent actions by PIA will be stopped. They are one of the reasons health care is so expensive today. This must stop.

Thank you.

Footnote:

Employer - Texas Instruments

Insurance - AETNA

Susan Alderson

Mr. SCHUMER. Let me first ask Dr. Marr some questions.

Dr. Marr, for somebody on your deathbed you look pretty good.

Dr. MARR. Thank you, sir.

Mr. SENSENBRENNER. Will the gentleman yield? That is not a clinical analysis.

Mr. SCHUMER. But I am not going to charge him for it, either.

Anyway, first, Dr. Marr, you really had a pretty good idea about what was going to happen at the clinic.

Dr. MARR. Yes, sir.

Mr. SCHUMER. I have found that the people in my community who know the most about these scams are former lab technicians. A retired lab technician came into my office about 3 weeks ago and said, she had gotten a bill back, which she was not responsible for paying, and she knew they had given her duplicate tests. But if I had seen that test I wouldn't know it. She knew it because of her work experience. You are in the same situation.

Just to inform my colleagues and the audience, Dr. Marr was victimized by a rolling lab scheme. They used to have these labs on wheels and go place to place and bring people in and bill and bill and bill. And when they became more successful, and they found out there was so much money in this, they built actual labs, such as the one Dr. Marr went to.

The rolling lab scheme that Dr. Marr was part of is one of the largest medical fraud cases ever recorded. I think it is the largest ever recorded. They are responsible for false billings of over \$1 billion, just in that one scheme.

As I understand, you are scheduled to testify for the prosecution in that case, is that correct, Dr. Marr?

Dr. MARR. Yes, sir, in late February 1993 it comes to trial.

Mr. SCHUMER. You mentioned that a doctor performed your physical exam while you were fully dressed.

Dr. MARR. That is correct.

Mr. SCHUMER. Is that standard medical practice?

Dr. MARR. Absolutely not, sir.

Mr. SCHUMER. It is not something new in southern California that we are not aware of? I know you are the originator of so much for the rest of the country.

Dr. MARR. Coming from Texas, it was a unique experience to me of what happens in California. However, to be charged \$295 for a physical examination while you are still dressed is a trick that I was not taught in medical school.

Mr. SCHUMER. Guess it saves time so they can get to the next fully dressed patient.

Dr. MARR. Surely.

Mr. SCHUMER. Let me ask you this. Aside from the illegal billings these labs rendered, was there any of the testing that was either medically unethical or even potentially harmful to the patient?

Dr. MARR. I think potentially harmful, yes.

First of all, I referred to the exercise stress test in an environment without a defibrillator or appropriate cardiac resuscitation equipment. One is stressed to their maximum, and it is not unheard of to have a cardiac arrest or acute myocardial infarction or other types of medical emergency develop under that type of situa-

tion, especially when you have physicians or people who are there who knew nothing about me.

So I would say, yes.

Mr. SCHUMER. You mentioned that some of the tests or diagnoses were unbundled for insurance payment reasons. Can you explain to us what that means?

Dr. MARR. Yes, sir. I will give you one specific example that I think will make it clear.

Normally, if a blood chemistry profile—which is a test where a small sample of blood is run through a computerized diagnostic piece of equipment that can give you back values of, let's say, 25 or 35 different blood chemistries—sugar, cholesterol, sodium, potassium, and so forth. At that time, what we call a profile 25 or 35 in California would cost somewhere between \$25 and \$35. These gentlemen billed for each of the components of this SMA-35 and generated a total bill of \$747 for something that the lab would normally bill them approximately \$25 if, in fact, it was actually run.

Mr. SCHUMER. From your knowledge, does this happen repeatedly in other places?

Dr. MARR. Yes, sir.

Mr. SCHUMER. I have heard of this in my own community, as well.

Dr. MARR. That is correct. It is commonly—it is a common abuse.

Mr. SCHUMER. Did the company ever tell you they would accept the 80-percent coverage from your insurance and waive the 20-percent copayment from you?

Dr. MARR. Yes, sir.

Mr. SCHUMER. Is that legal?

Dr. MARR. No, sir.

Mr. SCHUMER. Same in auto insurance, when they pad the bill and remove the deductible, and it is done here all the time.

Finally, you mentioned it is possible that a false diagnosis from one of these labs could lead to a person being denied health insurance in the future. Can you explain the seriousness of that kind of thing?

Dr. MARR. Yes, sir. I read in the news media a report of a gentleman who had gone through one of these labs. He later applied for insurance and these diagnoses had followed him into his application for insurance. And he was denied coverage based on some of the major diagnoses which appeared on these bogus health claims.

Mr. SCHUMER. Thank you.

Let me ask Ms. Alderson a few questions.

You mentioned you entered the treatment voluntarily. You were not committed.

Ms. ALDERSON. Yes.

Mr. SCHUMER. Why couldn't you just leave when you wanted to?

Ms. ALDERSON. They threatened me, for one thing, of having me committed if I tried to.

Mr. SCHUMER. If you tried to.

Ms. ALDERSON. I didn't know they couldn't do it, and, of course, my family was totally unaware of it. There were several things that they used to—

Mr. SCHUMER. You mentioned the wide disparity in charges for prescriptions. Some day, \$11, some days \$46. Did anyone ever explain to you the differences in the price of your bill? How did these prices compare with the price in your local pharmacy?

Ms. ALDERSON. I will be honest with you. I didn't see the bills until 1991. My oldest daughter was the one who had power of attorney, and she was the one who kept some but threw the great bulk of them away. She was very traumatized.

Mr. SCHUMER. How much does this cost you now?

Ms. ALDERSON. I have a special system with my insurance now. But, back then, a monthly run would be maybe \$20 or \$22.

Mr. SCHUMER. Instead they charged \$11 to \$46 a day.

Ms. ALDERSON. Right. And that was for 30 days.

Mr. SCHUMER. That is a 400- or 500-percent profit.

You mentioned what happened to the specific hospital. Do you feel that you received any therapeutic benefit from your stay in this hospital?

Ms. ALDERSON. No.

Mr. SCHUMER. To your knowledge, were you billed for any one-on-one counseling or group therapy that never took place?

Ms. ALDERSON. Yes. I went over the few bills I do have access to, and the therapy, the group therapies, were handled on an alternative basis by the doctors. There were three doctors in there. At times they were handled by nurses or psychologists and training therapists.

Mr. SCHUMER. OK. Thank you.

One final question. Did your insurance coverage limits come up often in the discussions with the medical staff? In other words, you were released just before you got to the \$50,000 limit on your insurance policy. Did you get any feeling that your being released was more related to how much insurance coverage you had, as opposed to how well you were getting?

Ms. ALDERSON. I got the feeling I was getting released because I had been turned down twice in a reclassification attempt and also a lawyer had been brought in and that was the last thing they wanted to be involved with.

Mr. SCHUMER. Well, thank you very much. It is not easy to tell this story. We appreciate your sharing it with us.

Mr. Sensenbrenner.

Mr. SENSENBRENNER. Dr. Marr, I am curious how you got to be selected to be the guinea pig for the fraud that was committed. You said in your testimony you were telemarketed. Do you have any idea how you were selected to be telemarketed?

Dr. MARR. At my employment, Pacific Mutual, I began to be told by many of our employees there that somebody had called them and asked them to go through a physical and laboratory testing, and it seemed to be an alphabetical situation.

When I went to one of these offices for testing, in the corner of the room was a large table with several telephones, and several men were sitting around it, and they were busily dialing. I just presumed that this was a boiler room type of operation where numerous people were soliciting folks just from the phone book.

In my case, I think at that time I had medical doctor, M.D., after my name in the phone book but, being randomly selected, that didn't seem to inhibit them.

Mr. SENSENBRENNER. That was my next question. I was going to ask if the people that gave you these examinations, quotes, "had any idea you were a medical doctor who presumably would know about these tests and exams."

Dr. MARR. First of all, I guess in the media I saw where some other medical physicians had been solicited, so I don't think my experience was unique. But when I did go through the rolling lab physical examination and was interviewed I gave my employer as Pacific Financial Co., which it was, and they asked what I did, and I said I worked on system enhancements, which was one of my responsibilities. But they did not know that I was a medical physician nor did they know that my wife, who went through this also, was a nurse.

Mr. SENSENBRENNER. So they never did call you Dr. Marr when you were in there?

Dr. MARR. No, sir.

Mr. SENSENBRENNER. Did you ask any questions of them while they were conducting these tests and this examination? Again, I use that term advisedly.

Dr. MARR. I did ask some questions. I tried to inquire from some of the technicians who performed some of the tests as to how many people a day would come through, and they would comment, 25 to 30 to 40, depending on the volume for that day. And the employees seemed to be willing to share some experiences, but some of the employees spoke with heavy foreign accents, and it was difficult for me to understand.

And one of the gentlemen, Mr. Spell, a gentleman who I referred to in here, told me my heart was enlarged—Mr. Winston Spell. He said that he had previously been at their Encino office before it was closed. I know they had a rolling lab in Encino which we were no longer getting bills from. Now he said he had to commute down to Santa Ana to do his work, and the commute was difficult for him. It was just that sort of conversation.

Mr. SENSENBRENNER. After you were diagnosed with all of these terrible maladies, was there a reference on to another physician or another clinic as a way of keeping the money coming in, to give you treatment for this diagnosis? Or, was this just a one-shot, cut-and-run thing where they would send in these bills for all of what they claimed to have done?

Dr. MARR. I told the folks that I was not under the care of a physician at that time, and they said they could provide me with the name of a doctor. However, I said that maybe it would be best for them just to send their reports to me and then I could take them to a doctor of my choice.

As I mentioned here, the rebilling continued for some over 2 years, and the rebilling would come in under different clinic names from different geographical locations from which they had originally occurred. Perhaps they had sold their accounts receivable, and I am speculating there, but different places would now bill us.

We even had one bill from out of State. It was—the bill didn't come to me. It went to our insurance company. But as an effort—

I think it was over a period of time—in breaking the denial that the insurance company had imposed.

Mr. SENSENBRENNER. Do you have any information that they did have a referral racket to a physician that either worked for this group or was an independent physician but in cahoots with the fraudulent lab, again to continue the money rolling in for treatment of a condition which may or may not have existed—as a result of the fraudulent lab tests?

Dr. MARR. The only personal information I have on that is a Dr. LeReuse, who was the chiropractor who saw us, told my wife she had one leg a little shorter than the other and it created curvature in her back and she needed treatments. And if she would come back there they could treat her at that office. And she said that is pretty far from where I live, and he reportedly said, well, you can't beat the price because we are not going to charge you anything. We will just bill your insurance company.

Mr. SENSENBRENNER. Could I ask—the chiropractor did not offer to treat your allegedly enlarged heart, did he?

Dr. MARR. No, sir.

Mr. SENSENBRENNER. Thank you.

Mr. SCHUMER. Mr. Smith.

Mr. SMITH. Thank you, Mr. Chairman.

Dr. Marr, you were obviously smart and shrewd enough to sense a health care fraud scam early on. It is clear from your testimony that you took notes, you kept names, and you knew pretty much early on what the scam was going to be and what the fraud involved.

How widespread do you think this is in the medical profession? And what made you suspicious of what you were getting into, in this particular instance?

Dr. MARR. There are two parts to your question. How widespread is this fraud—we see similar types of solicitations in various States even today. I received a claim on my desk this week at Mutual of Omaha for services from a provider in Arlington, TX. It was the same MO. Very same type of situation.

So even through all the publicity it still continues.

The second part of your question, sir, could you repeat that?

Mr. SMITH. The second part of my question had to do with what was the first thing that made you suspicious and made you suspect this was a health care scam?

Dr. MARR. Back in 1985 our claims—

Mr. SMITH. The reason for my asking the question is because I am wondering what other people can look to for a tipoff that there may be a health care scam coming along.

Dr. MARR. Yes, sir. In my personal, professional activities of claims involvement with Pacific Mutual, I was referred claims on a regular basis, and these fell into some suspicious patterns which would be unique and would alert us as claims payers.

However, as far as the public goes, I think any time that you are solicited to come in and get expensive testing for which you are not going to be responsible, which is not under the auspices of your personal physician whom you trust—

Mr. SMITH. Once again, very few things in life are free. The minute I get an offer that expensive health care is offered for free,

that is the "red flag" the public should be looking for to tip them off that a scam may be involved.

Dr. MARR. I think that is a good one. There was a lot of publicity in the papers in southern California, including the California Medical Association, the county medical societies, and in large advertisements alerting people to these scams, but people continued to take advantage of them.

Mr. SMITH. Dr. Marr, you are a physician yourself, so you are as aware, as I think the general public is, that 99 percent of the medical doctors in the country are honorable, trustworthy, compassionate and humane individuals. What we are talking about is a very small group of individuals in the profession that, frankly, bring dishonor to the profession. What recommendations—based on your experience as a doctor, what recommendations do you have as to how this system could be changed? What should we be looking for as a committee? What can we be doing?

I am not asking you for legal advice, but, just from your perspective as a physician, what recommendations do you have for us to try to eliminate some of this health care fraud that is so obviously in existence?

Dr. MARR. The chairman listed off several items which you folks apparently are focusing on with regards to legislation and enhancing the staff of the Inspector General and the dedication of inspectors with the FBI, et cetera.

Mr. SMITH. We will hear from the FBI shortly, and they have given renewed emphasis to health care fraud as well.

Dr. MARR. Yes, sir. I think definitely that sort of activity and legislation is most appropriate.

Mr. SMITH. Dr. Marr, lastly, we are going to hear in a few minutes from a representative of the American Medical Association, and one of the concerns he will raise is the question of intent. Is it difficult to prove a physician had intent to defraud a patient or not? Do we need to give the benefit of the doubt to the physician even though his or her judgment may be erroneous? How do you handle the question of intent? Do you think it can be resolved, and is it a problem?

Dr. MARR. Well, not being an attorney, it is difficult for me to comment on. However, I do believe where patterns repeat themselves of abuse then one must focus in on those patterns to suggest that this may actually be a deliberate attempt to defraud.

Mr. SMITH. Thank you, Dr. Marr.

Dr. MARR. Thank you, Mr. Smith.

Mr. SCHUMER. Mr. Schiff.

Mr. SCHIFF. Thank you, Mr. Chairman. I know we have other panels, and I will be brief.

I want to thank the witnesses. If I hear you correctly, you didn't go out of your way to identify yourself as a medical doctor when you went through this, and that is because you suspected the possibility of a fraudulent operation and didn't want to advise them of that fact. Do I have that about right?

Dr. MARR. Yes, sir. That is correct.

Mr. SCHIFF. Do you have any information whether this operation, if they had learned you were a doctor, would have said, thank you,

we don't need to see you anymore? If they knew you were a medical doctor, do you know what would have happened?

Dr. MARR. I honestly don't know.

Mr. SCHIFF. In the telemarketing solicitation you received, did you have the impression that it was by employer or just through the phone book or do you have any idea where the list came from that you were found on?

Dr. MARR. I just assumed it was the phone book based on what I visually saw in one of these clinics where a group of men were around tables and had large phone books and sitting there dialing. I didn't hear what the conversation was. They may have been dealing with something else. But I suspect the phone book was the source.

Mr. SCHIFF. Mr. Chairman, if I could have more time.

Mr. SCHUMER. You have more time.

Mr. SCHIFF. In the telemarketing was there any attempt to identify if you had insurance? How would they know that?

Dr. MARR. In the telemarketing, insurance was a primary concern. They asked, do you have insurance?

And let me share with you two experiences. The first one was while I was employed at Pacific Mutual. They said, do you have insurance? I said, yes, my company is Pacific Mutual. And they said, oh, that is good because they pay for our services. And as medical director of that company I was—I realized that we had paid for some of these in error.

When I was resolicited—I was employed at that time with Mutual of Omaha when I was resolicited in 1989. The comment was, oh, well, that is fine. Mutual of Omaha encourages their subscribers to take advantage of this outreach program to detect early illness so that large expenses are not needed later.

And this was totally false information.

Mr. SCHIFF. Thank you, Dr. Marr.

Ms. Alderson, if I may just come back. I believe you said—you referred to this facility as Brookhaven.

Ms. ALDERSON. That is the given name of it, Brookhaven Psychiatric Hospital.

Mr. SCHIFF. Is that facility still open?

Ms. ALDERSON. No, it isn't.

Mr. SCHIFF. Are there legal proceedings pending by the State of Texas for a determination of what happened to you and others in the State of Texas?

Ms. ALDERSON. The attorney general did settle, but there are numerous private proceedings going on against the doctor, the hospital, yes.

Mr. SCHIFF. I have one particular question over and above the possibility of fraudulent billings, which is bad enough, perhaps reflecting my prejudice as a former prosecutor. It seems to me if you were misdiagnosed to keep you in an institution so this billing procedure could continue, if all that is what happened, I would argue that that is false imprisonment. I just wonder if any prosecutor or government agency you talked with looked at it from that point of view?

Ms. ALDERSON. I am sure they did because there were numerous other cases of the same thing happening. In Texas the statute of

limitations is 2 years. When I got out of there all I wanted to do was forget about it or put it behind me if I could, which of course isn't—I never will be able to. But I do know there is a possibility I will be testifying in some cases.

Mr. SCHIFF. I understand. Thank you, Ms. Alderson.

Mr. Chairman, I yield back.

Mr. SCHUMER. Thank you. I have two quick followups.

Dr. Marr, is it clear that people's lives were being put in danger in the labs you visited?

Dr. MARR. Yes, sir, undoubtedly.

Mr. SCHUMER. Secondly, do you think there are other rolling labs that are as large in terms of the amount of fraud they produce as the one you came across? Is it possible?

Dr. MARR. Mr. Chairman, I am sure it is possible. I am not aware of anything as widespread as this operation was, and maybe Mr. Morey or people from the FBI could better comment on that.

Mr. SCHUMER. That is a useful segue to our next set of witnesses, so I wish to thank both, Dr. Marr and Ms. Alderson.

Did you want to say something else, Ms. Alderson?

Ms. ALDERSON. This is being investigated right now in the State of Texas.

Mr. SCHUMER. This same type of fraud? Rolling labs?

Ms. ALDERSON. Yes, exactly.

Mr. SCHUMER. Thank you both very much.

Dr. MARR. Thank you.

Mr. SCHUMER. Our second panel this morning consists of representatives of government agencies which investigate health care fraud, and we want to thank them for coming. They are doing a very difficult job with minimal resources, and we very much appreciate them being here.

Mr. Larry Potts is an Assistant Director of the FBI in charge of the Criminal Investigative Division here in Washington. During his 19 years in the FBI he has worked in various field offices and headed up the FBI Public Corruption and White Collar Crimes units. He was also honored for his work on the Federal Mail Bombing Task Force.

Larry Morey is Deputy Inspector General for Investigations at the U.S. Department of Health and Human Services and has been in that position since December 1981. His office is charged with investigating criminal wrongdoing against programs of the Department of Health and Human Services, including Medicare and Medicaid fraud. He has also been honored, receiving an award for detection and prevention of fraud and waste in government programs. He spent 12 years with the FBI before moving to HHS.

Finally, Janet Shikles is Director of Health Financing and Policy Issues for the U.S. General Accounting Office. Her office conducts audits and valuations of Medicare, Medicaid and national health policy issues. She also has worked as senior analyst in research for HHS. She has also worked on health issues at the local government level.

I want to thank each of you for coming here. Your statements will be inserted in the record without objection.

I know you, Mr. Potts, have to catch a train to Philadelphia. With indulgence of the other witnesses, maybe Mr. Potts will be allowed to testify first. What time do you have to be there?

Mr. POTTS. I don't have to leave for another hour, so I am fine.

Mr. SCHUMER. Let's go through the regular order, but you are on first. Thank you very much for being here.

**STATEMENT OF LARRY A. POTTS, ASSISTANT DIRECTOR,
CRIMINAL INVESTIGATIVE DIVISION, FEDERAL BUREAU OF
INVESTIGATION**

Mr. POTTS. Thank you, Mr. Chairman. I appreciate very much the opportunity to appear before your committee today.

I have just a very few brief remarks that I would like to make and then, as you said, enter my entire prepared statement for the record.

Prior to outlining the magnitude of the problem, I want to stress that the FBI does not intend to second guess the sound professional practices of hard-working health care providers. In fact, the vast majority of health care providers are honest, hard-working professionals and business people.

The FBI is working very closely with the health care industry and trade associations, including the American Medical Association, National Health Care Anti-Fraud Association, in coordinating our endeavors, and we will continue in these efforts.

Mr. SCHUMER. Could you pull the mike a little closer? People in the back are having trouble hearing you.

Mr. POTTS. Some of the—Mr. Chairman, I think that it is interesting to note that this is certainly one area where we see almost the maximum amount of cooperation among the various entities. My friend, Larry Morey, and I have known each other for a long time. There is an excellent relationship with the HHS, IG, the various State investigators, and I think we are developing an ever better relationship with the private carriers as well as the State Medicaid investigators.

During the past 3 years the FBI has made significant strides in training investigators and prosecutors, encouraging private health care insurers to join in law enforcement efforts, investigating cases, recouping hard cash and sending to jail those involved in defrauding the health care system.

In the past 10 months the FBI has sponsored health care fraud training seminars which have jointly been attended by approximately 750 FBI agents, Federal and State investigators and prosecutors, as well as investigators for private health insurers. The FBI is also involved with private insurers in enforcement efforts by unifying alliances where mutual goals are the same.

During April and October 1992, the FBI sponsored symposiums at its FBI Academy, and approximately 50 private health insurance executives provided valuable insight as to the types of criminal enterprises that drain insurance and public programs. Within the past 2 months the FBI has sponsored strategy meetings with the Department of Justice, private health insurance and President Clinton's transition health care policy group to discuss a comprehensive focus of resources through effective enforcement and legislation.

During 1992, the fruits of our investigative endeavors were reflected in many significant cases brought before the public's attention. We prepared a chart, and it is the middle chart here, showing the growth in the FBI's—the one on the left—showing the growth in the health care fraud achievements over the past 2 years.

Frankly, the FBI's use of undercover operations and other sophisticated techniques has uncovered fraud in virtually every segment of the health care industry. Although our accomplishments demonstrate dramatic increases, we realize we have only touched the tip of the iceberg in this particular problem.

I think it is important to note that we added additional resources. The Director reprogrammed resources in February of last year, a year ago this month, and at that particular time we had about 50 agents working health care fraud on a national basis. We reprogrammed 50 agents and then we have really drained resources from other areas of government fraud and white-collar crime in order to put them over on health care fraud to the point where we have about 150 agents working health care fraud cases now.

The results, I think, are somewhat dramatic. I doubt you can see that, but in 1991 we had a total of 82 indictments in health care fraud matters, and in 1992 that total went up to 409. I think that you will see those continue to rise as the resources continue to work these cases.

The Nation's health care industry is infected by unscrupulous business people and providers. This chart reflects the types of common health care, the middle chart, the types of frauds the FBI has uncovered: Fraud in billing schemes by durable medical equipment suppliers, nursing home scams, hospital billing frauds, psychiatric hospital and diet clinic scams, laboratory frauds, pharmaceutical frauds, corrupt billing schemes by physicians, rolling lab scams which prey on the elderly and defrauded Medicare and private insurers and home health care schemes.

The FBI's Goldpill undercover operation uncovered billing frauds and drug diversion schemes involving hundreds of individuals swindling the Medicaid system and private insurance plans. Adulterated and expired drugs intended for sale to the public were located and seized from unsanitary storage conditions.

The New York Goldpill case, you can see from this last chart, that was one example of many locations where we found drugs from that particular investigation and the temperature inside that particular building went up to as much as 130 degrees Fahrenheit and the conditions were extremely unsanitary. The various medicines were mixed and not marked, and these were ready to go back on the market.

The New York Goldpill case used court-ordered telephone taps to broaden its investigation. In written affidavits that supported the arrests, subjects were quoted speaking to pharmacists and other diverters about their activity. One diverter stated to a pharmacist, "it comes off the street. It is not what I order and they deliver it. It comes from a Medicaid center."

Another diverter is quoted as saying, "this is street goods, you know, from the street people. If they don't get it—street goods are not like ordering from a wholesaler."

Two others are quoted mocking criminal penalties as saying, "most of the time you get 20 to life, you walk out on your own recognition."

Later in the same conversation the diverters discuss the vast amounts of cash being generated by the fraud scheme and said that they could not keep "putting twenties in their vault box because it would take up too much space." One diverter remarked, "you will have to have a mausoleum."

Our investigation found health care frauds are perpetrated by telemarketing promoters. They often target the elderly. They con the public into believing they need durable medical equipment while their insurance covers the expense, and in some cases doctors have been unwitting victims. In other cases, doctors have received kickbacks for the equipment they prescribe.

For example, DME business can purchase a tens unit. This is an example of a tens unit. I am not sure if you are familiar with this. This is a tens unit that came from a case in Detroit. This particular durable medical equipment provider went to Korea, and he purchased this for \$22 with battery included. And he came back and he launched a scheme where doctors would prescribe this particular unit. And this unit frequently is given to people with arthritis, to stimulate the nerves. And for \$22 he billed the insurance companies between \$400 and \$600.

That, obviously, leaves plenty of room for kickbacks to firms who will prescribe this, and that still leaves plenty of profit for this particular individual who since has been convicted.

Health care fraud schemes can have an enormous economic impact on the Government and private insurer. In a recent joint investigation, National Health Laboratories pled guilty to submission of false claims for blood tests. They billed between \$12 and \$22 for individual tests. During the course of the fraud scheme, hundreds of millions of dollars in blood tests were billed to the Government. In a negotiated settlement agreement, NHL agreed to pay a combined civil fine of \$111.5 million. A \$12 scheme resulted in millions in phony billings to the Government.

Investigators have also uncovered criminal activities in hospitals, nursing homes, diet clinics and psychiatric facilities.

Many of today's health care fraud cases are complex, labor intensive and require not months but years to investigate and prosecute. Law enforcement requires resources to address current health care frauds as well as resources to meet future challenges.

As an example, by the year 2000 health care providers will have the ability to access private insurers data bases, file health claims and receive payments electronically without benefit of having claims ever being physically reviewed. These advantages in business technology offer new opportunities for the fraudster to exploit loopholes scoring enormous profits in a paperless environment and with a paperless trail.

The FBI along with the National Health Care Anti-Fraud Association and private industry sources and the IG for HHS are working to improve electronic fraud detection.

To assist in short-term results, the FBI proposes developing these capabilities that would detect questionable activity on single

claim submissions. The approach would increase identification in isolated instance of fraud.

A second step would be coordinated effort by Federal law enforcement and the private sector in combination with scholastic research in the advent of electronic claims processing which would be able to somehow develop a proactive program for us and indicate where the major frauds are occurring and allow us to get at them at a very early stage.

The FBI will continue using sophisticated techniques to get our evidence needed to prosecute the crimes. The public must get involved and report fraud activity to authorities. I hope that information we provide in this hearing today and information that we provide separately will somehow help the members of this committee, Mr. Chairman, to know that we are committed to this problem.

We understand the enormous size of it. It is somewhat overwhelming at times. And we are prepared to go forward and work this with all the resources that we have available.

Mr. SCHUMER. Thank you, Mr. Potts.

[The prepared statement of Mr. Potts follows:]

PREPARED STATEMENT OF LARRY A. POTTS, ASSISTANT DIRECTOR,
CRIMINAL INVESTIGATIVE DIVISION, FEDERAL BUREAU OF INVESTIGATION

MR. CHAIRMAN, I APPRECIATE THE OPPORTUNITY TO APPEAR BEFORE YOUR COMMITTEE TO DISCUSS THE FBI'S EFFORTS IN STEMMING THE ORGANIZED "BUSINESS" FRAUDS AFFECTING THE HEALTH CARE INDUSTRY. AMERICANS HAVE EVERY RIGHT TO HAVE ACCESS TO AFFORDABLE HEALTH CARE. THE FBI LAUDS YOUR SUPPORT IN PURSUING THOSE WHO WOULD VIOLATE BUSINESS ETHICS AND DESECRATE THEIR HIPPOCRATIC OATHS. PRIOR TO OUTLINING THE MAGNITUDE OF THE HEALTH CARE FRAUD PROBLEM, I WANT TO STRESS THE FBI DOES NOT INTEND TO SECOND-GUESS THE SOUND PROFESSIONAL PRACTICES OF HONEST HARD-WORKING HEALTH CARE PROVIDERS. IN FACT THE VAST MAJORITY OF HEALTH CARE PROVIDERS ARE HONEST HARD WORKING PROFESSIONALS AND BUSINESSMEN.

THE FBI IS WORKING IN A CLOSE COOPERATIVE EFFORT WITH INDUSTRY GROUPS, SUCH AS THE AMERICAM MEDICAL ASSOCIATION TO IDENTIFY CRIMINAL PROBLEMS AND BRING CORRUPT HEALTH CARE PROFESSIONALS AND BUSINESSMEN TO THE BAR OF JUSTICE.

THE FEBRUARY 1992 REPROGRAMMING OF AGENTS TO COMBAT HEALTH CARE FRAUDS AND THE ENDEAVORS OF THE FBI'S RECENT "GOLDPILL" CASES HAVE PROVIDED A STRONG GENESIS IN ESTABLISHING THE FBI'S "HEALTH CARE FRAUD INITIATIVE".

AS THE GOLDPILL CASES HAVE DEVELOPED, THE FBI HAS IDENTIFIED FRAUD SCHEMES IN MANY SEGMENTS OF THE HEALTH CARE INDUSTRY.

HEALTH CARE FRAUDS

WE HAVE PREPARED A CHART WHICH REFLECTS THE TYPES OF COMMON HEALTH CARE FRAUDS THE FBI HAS UNCOVERED: FRAUDULENT

BILLING SCHEMES BY DURABLE MEDICAL EQUIPMENT SUPPLIERS; NURSING HOMES SCAMS; HOSPITAL BILLING FRAUDS; PSYCHIATRIC HOSPITAL AND DIET CLINIC SCAMS; LABORATORY FRAUDS; PHARMACEUTICAL FRAUDS; CORRUPT BILLING SCHEMES BY PHYSICIANS; ROLLING LAB SCAMS WHICH PREY ON THE ELDERLY AND DEFRAUD MEDICARE AND PRIVATE INSURERS; WORKMEN'S COMPENSATION FRAUDS; HOME HEALTH CARE SCHEMES; AND, MANY OTHER FRAUDS BY CORRUPT BUSINESSES WHICH PROVIDE ANCILLARY SERVICES TO THE HEALTH CARE INDUSTRY.

DURABLE MEDICAL FRAUDS (DME) AND KICKBACKS

INVESTIGATIONS AND THE INTELLIGENCE BASE HAVE SHOWN THAT DME FRAUD IS A SIGNIFICANT CRIMINAL PROBLEM. DME FRAUDS ARE PERPETRATED THROUGH SEVERAL SCHEMES. DME COMPANIES OFTEN PAY KICKBACKS TO DOCTORS, NURSING HOMES, AND HOSPITALS FOR OBTAINING SUPPLY CONTRACTS. MEDICARE AND PRIVATE INSURANCE COMPANIES ARE PROGRAMS EASILY TARGETED BY THESE UNSCRUPULOUS BUSINESSMAN. (SHOW TENS UNIT -- MANUFACTURED FOR APPROXIMATELY \$65-100 AND BILLED TO MEDICARE OR THE INSURANCE COMPANY FOR BETWEEN \$450-\$600 -- ALLOWING DME FIRMS TO PAY KICKBACKS WITH ROOM FOR SUBSTANTIAL PROFITS). SUBJECTS HAVE BEEN KNOWN TO USE AGGRESSIVE TELEMARKETING SCAMS TO FRAUDULENTLY BILL UNNECESSARY DME SUPPLIES AND SERVICES. OTHER SUBJECTS OBTAIN PATIENT LISTS FROM NURSING HOMES AND ROUTINELY BILL FOR PRODUCTS OR SERVICES WHICH ARE NEITHER NEEDED OR PENDERED.

PSYCHIATRIC HOSPITALS

IN RECENT YEARS, HEALTH CARE BENEFITS HAVE EXPANDED TO COVER TREATMENTS FOR SUBSTANCE ABUSE, ALCOHOLISM, AND MENTAL DEPRESSION. GENERALLY, HEALTH INSURANCE ALLOWS FOR COVERAGE OF

IN-PATIENT TREATMENT UP TO 28 DAYS ENABLING HOSPITALS TO COLLECT UP TO \$40,000 PER PATIENT. GREEDY BUSINESSMEN PREY ON THOSE WEAKNESSES AS A VEHICLE TO GARNER SUBSTANTIAL PROFITS. UNFORTUNATELY, IT IS THOSE BUSINESSMEN AND PROFESSIONALS WHO WOULD DEFRAUD GOVERNMENT PROGRAMS AND PRIVATE INSURERS OF HUNDREDS OF MILLIONS OF DOLLARS ANNUALLY IN IN-PATIENT HOSPITALIZATION, WHEN OUT-PATIENT TREATMENT WOULD BE MORE APPROPRIATE. PATIENTS HAVE BEEN FORCIBLY ADMITTED INTO PSYCHIATRIC TREATMENT PROGRAMS IN SITUATIONS WHERE THEY POSED NO THREAT TO THE COMMUNITY OR THEMSELVES.

OFTEN PATIENTS ARE SUBJECT TO BATTERIES OF BLOOD TESTS, X-RAYS, SHOCK TREATMENT, AND OTHER SERVICES. ONE SUCH TREATMENT INVOLVES THE DOCTOR PROVIDING THE PATIENTS "WAVE" THERAPY. THE TREATMENT WHILE RELATIVELY PAINLESS, IS VERY EXPENSIVE. MR. CHAIRMAN, THE DOCTOR WILL, WITH A SIMPLE "WAVE" OF HIS OR HER HAND DURING ROUTINE ROUNDS, SUBMIT BILLS TO THE GOVERNMENT PROGRAM OR INSURANCE COMPANIES FOR \$125 IN INDIVIDUAL THERAPY. PRIVATE INSURERS HAVE PROVIDED ALLEGATIONS INVOLVING MILLIONS OF DOLLARS OF FRAUDULENT BILLINGS.

DIET CLINICS

DIET CLINICS INVOLVED IN CRIMINAL ACTIVITY PERPETUATE FRAUD BY SOLICITING PATIENTS -- USUALLY THROUGH MASS MEDIA, AND PROMISE WEIGHT LOSS AT NOMINAL EXPENSE TO THE PATIENT. CUSTOMERS WHO FREQUENT DIET CLINICS ARE OFTEN REQUIRED TO UNDERGO A CURSORY PSYCHOLOGICAL EXAMINATION, A SERIES OF BLOOD TESTS, X-RAYS AND OTHER ANCILLARY TESTS. THESE SERVICES ARE THEN BILLED TO INSURERS UNDER THE FALSE PRETENSE OF A MANUFACTURED

PSYCHOLOGICAL MALADY.

THE CLINICS SOLICIT PATIENTS PROMISING AN IN-HOUSE RESPITE AT A COUNTRY CLUB-TYPE FACILITY. PATIENTS ARE PROVIDED AIRFARE -- AT NO EXPENSE, AND ARE OFTEN PROVIDED A CHAUFFEURED LIMOUSINE TO THE HOSPITAL. GROUP THERAPY SESSIONS SUCH AS TRIPS TO SHOPPING MALLS, AMUSEMENT PARKS, DEEP SEA FISHING EXCURSIONS ARE BILLED AS TREATMENT FOR MENTAL ILLNESS. THE HOSPITAL STAY AS WELL AS ALL SERVICES PROVIDED ARE BILLED TO PRIVATELY INSURED CARRIERS BASED UPON A PURPORTED PSYCHIATRIC DIAGNOSIS WHEN IN FACT THE PATIENTS WERE AT THE CLINIC TO LOSE WEIGHT.

THE CLINICS ACCOMPLISH THE FRAUD BY MISREPRESENTING THE MEDICAL CONDITIONS OF THEIR CUSTOMERS IN ORDER TO JUSTIFY PAYMENTS FOR THE TESTS AND OTHER SERVICES. WHEN CONDUCTING THESE INVESTIGATIONS THE FRAUDS ARE SO CRAFTED, IT BECOMES DIFFICULT TO DIFFERENTIATE CONCERN FOR THE PATIENTS RECOVERY AND BUSINESS PROFITS IN GATHERING THE EVIDENCE. MANY CASES ARE SOLVED BY THE COOPERATION OF HONEST EMPLOYEES AND THE USE OF SOPHISTICATED INVESTIGATIVE TECHNIQUES. INVESTIGATIONS HAVE DISCOVERED THAT TAXI, LIMOUSINE AND SHUTTLE BUS SERVICES, ARE OFTEN DISGUISED IN BILLINGS TO INSURANCE COMPANIES AS AMBULANCE SERVICES. TO DATE, FRAUDS OF THIS NATURE HAVE BEEN DOCUMENTED IN THE MILLIONS BY PRIVATE INSURANCE COMPANIES.

PHARMACEUTICAL DIVERSIONS AND PHARMACY BILLING FRAUD

THE FBI'S EFFORTS IN OPERATION GOLDPILL MAY BEST ILLUSTRATE THE BREADTH OF CRIMINAL ACTIVITY CONTAMINATING THE HEALTH CARE INDUSTRY.

OPERATION GOLDPILL BASICALLY INVOLVES TWO TYPES OF

MEDICAL FRAUD SCHEMES. THE FIRST INVOLVES THE DIVERSION OF NON-CONTROLLED PHARMACEUTICAL MEDICATIONS, THE KIND OF NON-NARCOTIC DRUGS YOU AND I OBTAIN LEGALLY THROUGH A DOCTOR'S PRESCRIPTION.

THE NEW YORK GOLDPILL CASE USED COURT-ORDERED TELEPHONE WIRETAPS TO BROADEN ITS INVESTIGATION. IN WRITTEN AFFIDAVITS SUPPORTING THE ARRESTS, SUBJECTS WERE QUOTED SPEAKING TO PHARMACISTS AND OTHER DIVERTERS ABOUT THEIR ACTIVITY.

ONE DIVERTER STATED TO A PHARMACIST "...IT COMES OFF THE STREET. IT'S NOT THAT I ORDER FROM THE COMPANY AND THEY DELIVER. ...IT COMES OUT OF A MEDICAID CENTER"

ANOTHER DIVERTER IS QUOTED AS SAYING "...THIS IS STREET GOODS, YOU KNOW..." FROM "...THE STREET PEOPLE, IF THEY DON'T GET IT...STREET GOODS AREN'T EXACTLY ORDERING FROM A WHOLESALER."

TWO OTHER DIVERTERS ARE QUOTED MOCKING CRIMINAL PENALTIES AS SAYING "...MOST OF THE TIME YOU GET TWENTY YEARS TO LIFE YOU WALK OUT ON YOUR OWN RECOGNIZANCE." LATER IN THE SAME CONVERSATION THE DIVERTERS DISCUSSED THE VAST AMOUNTS OF CASH BEING GENERATED BY THE FRAUD SCHEME AND SAID THEY COULD NOT KEEP PUTTING TWENTIES IN THEIR "VAULT BOX" BECAUSE IT WAS TAKING UP SO MUCH SPACE. ONE DIVERTER REMARKED "YOU'RE GOING TO HAVE TO HAVE A MAUSOLEUM."

OUR INVESTIGATIONS SHOW THIS CRIMINAL ACTIVITY IS OCCURRING IN MAJOR METROPOLITAN AREAS THROUGHOUT THE UNITED STATES.

THE SECOND PERVASIVE CRIMINAL ACTIVITY "GOLDPILL" FOCUSED ON IS THE FRAUDULENT SUBMISSION OF BILLS BY PHARMACIES.

THIS SCHEME DELIBERATELY DEFRAUDS FEDERALLY FUNDED MEDICAID PROGRAMS AND PRIVATE INSURANCE CARRIERS, DRIVING UP THE COSTS OF HEALTH CARE TO ALL CONSUMERS AND TAXPAYERS.

DOCTORS

PHYSICIAN FRAUDS REVOLVE AROUND THE SUBMISSION OF FALSE CLAIMS. FALSE BILLINGS BY DOCTORS GENERALLY OCCUR WHEN: THE SERVICE WAS NEVER RENDERED; A SERVICE WAS IN FACT RENDERED, BUT A MORE EXPENSIVE PROCEDURE (UNPERFORMED) WAS BILLED; THE SERVICE WAS PERFORMED FEWER TIMES THAN IT WAS BILLED; THE DIAGNOSIS CODE ON THE BILLING IS ALTERED TO PURPORTEDLY JUSTIFY MORE EXPENSIVE TREATMENT AND PROCEDURES; THE SERVICE WAS NOT RENDERED BY THE QUALIFIED PROFESSIONAL BUT WAS RENDERED BY A LESSER OR UNQUALIFIED INDIVIDUAL; PROVIDERS BILLING FOR PATIENT EXAMINATIONS WHEN NONE HAVE BEEN PERFORMED; PHYSICAL THERAPISTS PERFORMING TWO MODES OF THERAPY ON A PATIENT AND THEN BILLING FOR FOUR SEPARATE PROCEDURES; TO CITE TWO EXAMPLES: THERE IS THE PHYSICIAN REPRESENTING THAT A MORE EXPENSIVE PLASTER CAST WAS PLACED ON THE PATIENT RATHER THAN THE LESS EXPENSIVE SPLINT; AND, PODIATRISTS BILLING FOR EXTENSIVE MEDICAL PROCEDURES WHILE SIMPLY CLIPPING A PATIENTS TOENAILS. THE SCHEMES AND METHODS OF BILLING FRAUDS ARE LIMITED ONLY TO YOUR IMAGINATION.

LABORATORY SCAMS

ONE EXAMPLE OF A TYPICAL LAB SCAM INVOLVES MEDICAL LABORATORIES WHO "SINK TEST", A PROCEDURE WHICH ESSENTIALLY INVOLVES DUMPING BLOOD AND URINE SPECIMENS DOWN THE SINK WITHOUT PERFORMING THE TESTS AND THEN REPORTING TEST RESULTS WITHIN THE NORMAL RANGE. IT IS NOT UNCOMMON THAT LABS AGREE TO PAY

KICKBACKS TO CLINIC OWNERS OR DOCTORS FOR PERFORMING EXTENSIVE BLOOD WORK, URINE TESTS OR X-RAYS. PATIENTS THEMSELVES ACCEPT CASH FOR PROVIDING THEIR MEDICARE/MEDICAID CARDS TO THE CLINIC OR LAB OWNERS.

ROLLING LABS

SENIOR CITIZENS HOMES AND POOR NEIGHBORHOODS ARE OFTEN EASY TARGETS FOR ROLLING CLINICS AND LABS. WITH "BABY BOOMERS" REACHING RETIREMENT AGE, SENIOR CITIZEN HOMES ARE FAST BECOMING A GROWING INDUSTRY. THE INTELLIGENCE BASE HAS ALSO INDICATED SUBSTANTIAL FRAUD BY THESE ENTREPRENEURS. OPERATORS OF ROLLING LABS ADVERTISE FREE MEDICAL TESTING AND "SCREENING" AND OFTEN "SCREEN" THE PATENT FOR MEDICARE, MEDICAID OF PRIVATE INSURANCE COVERAGE. ONCE THEY OBTAIN THE INSURANCE INFORMATION, THEY PERFORM AND BILL FOR MANY UNNECESSARY MEDICAL TESTS. IT IS COMMON FOR THESE BUSINESSMEN TO PERPETRATE THEIR FRAUDS BY PAYING KICKBACKS TO THE SENIOR CITIZEN HOME'S MANAGERS OR BILL FOR PHONY SERVICES.

WORKERS COMPENSATION AND ACCIDENT CLAIMS

PRIVATE INSURERS AND THE GOVERNMENT LOSE MILLIONS OF DOLLARS ANNUALLY TO PHONY AUTOMOBILE AND "SLIP-AND-FALL" CLAIMS. ONGOING INVESTIGATIVE MATTERS AND THE INTELLIGENCE BASE INDICATE THAT THE FEDERAL GOVERNMENT, STATES, AND PRIVATE INSURERS LOSE BILLIONS OF DOLLARS IN MEDICAL AND LIABILITY CLAIMS ANNUALLY TO MEDICAL DOCTORS, LAWYERS, AND PARTIES FAKING INJURY. NORMALLY, TO AVOID LITIGATION COSTS, INSURANCE COMPANIES GENERALLY AGREE TO SETTLE CLAIMS THROUGH ARBITRATION. THE COOPERATING DOCTOR AND ATTORNEY WILL HAVE CONSPIRED IN STRUCTURING THE FRAUD AND THE

ARBITRATOR GENERALLY IS NOT ABLE TO DETERMINE THAT THE CLAIM IS INVALID.

HMO PATIENT SCREENING

PATIENTS WHO OBTAIN TREATMENT THROUGH HEALTH MAINTENANCE ORGANIZATIONS (HMO) AND PREFERRED PROVIDER MAINTENANCE ORGANIZATIONS (PPMO) MAY BE PART OF A CRIMINAL ACTIVITIES IN THE "SCREENING" OF PATIENTS MEDICAL HISTORY. BOTH HMOS AND PPMOS ARE MULTI-PURPOSE PROVIDER ORGANIZATIONS WHICH CHARGE REDUCED FEES FOR SERVICES BECAUSE THEY SERVICE LARGE GROUPS OF THE PATIENT POPULATION. THE HMOS PROFITS ARE GREATER WHEN FEWER PROCEDURES ARE PERFORMED ON MEMBER PATIENTS. THEREFORE, THE HEALTHIER THE PATIENTS, THE MORE PROFITABLE THE HMO BECOMES. "SCREENING" IS THE FRAUDULENT PRACTICE THAT THE HMO PERFORMS WHEN IT EXCLUDES OR "SCREENS" THE SICK PATIENTS AND ACCEPTS ONLY THE HEALTHY PATIENTS. THE HMO FALSELY REPORTS TO THE INSURERS, HOWEVER, THAT IT HAS NOT DISCRIMINATED AGAINST INDIVIDUALS BY NOT PROVIDING SERVICES TO OTHERWISE QUALIFIED PERSONS.

HOSPITAL AND NURSING HOME FRAUDS

NURSING HOMES AND HOSPITALS OFTEN BILL INSURERS OR FEDERAL GOVERNMENT PROGRAMS. FRAUDS REVOLVE AROUND THE SUBMISSION OF FALSE CLAIMS. FALSE BILLINGS BY HEALTH CARE PROVIDERS GENERALLY OCCUR WHEN AGAIN: SERVICES WERE NEVER RENDERED; A SERVICE WAS RENDERED, BUT A MORE EXPENSIVE PROCEDURE WAS BILLED; THE SERVICE WAS PERFORMED FEWER TIMES THAN IT WAS BILLED; THE DIAGNOSIS CODE IS ALTERED TO JUSTIFY MORE EXPENSIVE TREATMENT AND PROCEDURES; OR, THE SERVICE WAS NOT RENDERED BY THE

QUALIFIED PROFESSIONAL BUT WAS RENDERED BY LESSER OR UNQUALIFIED INDIVIDUAL.

HOME HEALTH CARE AND AMBULANCE SERVICES

HOME HEALTH CARE IS FAST BECOMING AN ALTERNATE PRESCRIPTION FOR OUT-PATIENT HOSPITAL TREATMENT. ONCE AGAIN, NO RECIPE FOR IMPROVING PATIENT CARE CAN EXIST WITHOUT ADDING THE FRAUD INGREDIENT. ALLEGATIONS ARE BEING MADE THAT HOME HEALTH CARE PROVIDERS FRAUDULENTLY BILL FOR SERVICES NOT RENDERED, PAY KICKBACKS TO HOSPITAL STAFF AND DOCTORS FOR PATIENT REFERRALS, AND BILL FOR A SERVICE WHICH WAS PERFORMED FEWER TIMES THAN IT WAS PROVIDED. ANOTHER AREA SUSCEPTIBLE TO FRAUD INVOLVES AMBULANCE COMPANIES BILLING FOR EMERGENCY CONVEYANCE WHEN NO "EMERGENCY" EXISTED, TRIPS INVOLVING NON-EXISTENT OXYGEN USE, AND CHARGING FOR HIGHER THAN AVERAGE MILEAGE PER TRIP. IN A RECENT INVESTIGATION, AN AMBULANCE COMPANY ENGAGED IN THREATENING AND BEATING EMPLOYEES OF THEIR COMPETITORS TO ESTABLISH TERRITORY IN A MASSIVE MEDICAID FRAUD SCHEME.

CONCLUSION

MR. CHAIRMAN, I HAVE TOUCHED ON JUST A FEW OF THE SEGMENTS OF THE HEALTH CARE INDUSTRY WE ARE ACTIVELY INVOLVED IN INVESTIGATING. THERE ARE STILL MANY OTHER BRANCHES IN THE INDUSTRY WHERE ALLEGATIONS HAVE SURFACED AND WEAKNESSES HAVE BEEN DETECTED. THOSE AREAS WILL REQUIRE FURTHER REVIEW AND INQUIRY. WHILE I HAVE BEEN SOMEWHAT GUARDED ABOUT PRESENTING SPECIFIC CASES; I HOPE THAT THE INFORMATION PROVIDED WILL ASSURE THE MEMBERS OF THIS COMMITTEE THAT THE FBI IS COMMITTED TO PURSUING AGGRESSIVELY HEALTH CARE FRAUD INVESTIGATIONS. MR. CHAIRMAN, THIS CONCLUDES MY REMARKS AND I WOULD ALSO BE PLEASED TO RESPOND TO ANY QUESTIONS YOU MAY HAVE AT THIS TIME.

Mr. SCHUMER. Mr. Morey.

STATEMENT OF LARRY D. MOREY, DEPUTY INSPECTOR GENERAL FOR INVESTIGATIONS, OFFICE OF INSPECTOR GENERAL, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Mr. MOREY. Good morning, Mr. Chairman and members of the committee. I appreciate the opportunity to testify on health care fraud this morning. I have submitted my written statement and would request that you enter it into the record.

Mr. SCHUMER. Without objection that will be done.

Mr. MOREY. Identifying health care fraud is one of the top priorities for the Office of the Inspector General at HHS. As the Deputy Inspector General for Investigations it is my responsibility to identify fraud and then to investigate it.

I am certainly in agreement with the testimony I have heard this morning concerning the seriousness of health care fraud and the impact it is having on our Nation. I personally believe we are falling further and further behind in our battle against health care fraud. If we look over the last 10 years, our statistical accomplishments have risen remarkably. For example, health care criminal convictions in 1981 were about 20. They have increased to last year to 168. That is approximately an 800-percent increase. The fact of the matter is over the last 10 years we have had an increase each year.

Now there is even a more dramatic increase here and that is occurring in those who would abuse our programs but whose wrongdoing falls far short of that which is necessary for criminal prosecution. For example, in 1992 we had over 1,700 administrative sanctions where we sanction people out of the health care program. That means those operators now can only do business with the private sector. That is 44 times greater than what it was in 1981.

As you look at that tremendous need that we have to administratively sanction health care providers, I think we get the sense we are not winning this health care fraud battle. However, at a time when our Department's outlays are increasing—for example, this year \$41 billion—the Office of the IG finds their funding is level funding. We have had that problem for the last 3 years.

Now the effect of the level funding on my office means I had to reduce employees by 70, which is a 15-percent decrease in the total employees that I have now in the Office of Investigations. Probably even a more significant number is that I have 17 percent less investigators on the street this year than I did last year.

I have other data that I think personally are very shocking. For example, it is shocking to me that the Office of Investigations has one special agent for every 500,000 Medicare and Medicaid beneficiaries, that I have one special agent for every \$2 billion of departmental outlays.

For example, we have about one million health care providers in the health care area alone. That would equate to 1 street agent for every 8,700 health care providers out there. There is no way that we can keep up with this.

Last year we paid contractors \$1.4 billion to pay health care claims. They paid 600 million medical claims last year. With that

tremendous number of claims we know it is vulnerable to all the abuses and fraud that we can think of.

I throw the numbers out just to indicate to you the great challenge that my office feels we are under to be successful with these situations.

Over the years I do believe that the OIG has been a good investment for Congress. For example, in 1992, with fines, savings, restitutions, settlements that we have had, we returned \$61 for every dollar Congress invested in our organization. We have had 16 years of health care experience. We do a good job. We have been successful in the past, and I would give you four areas in the Medicare area that we believe have deficiencies.

One, some payments are excessive. Two, we have unnecessary and inappropriate care rendered to beneficiaries. Number three, we have financial conflicts of interest. Four, Medicare systems are vulnerable to manipulation. They just are.

To reduce the fraud, waste, and abuse, I have provided in my written statement several recommendations for your consideration. I would suggest that we continue to support the private sector in their effort to fight health care fraud. We certainly need everyone involved in this if we are going to win this.

The National Health Care Anti-Fraud Association is the prime example where the public and private sector did get together with the thoughts in mind of fighting health care fraud. Their efforts are noteworthy, and they should be noted.

In closing, I would say that the OIG has been on the front line of this battle for the past 16 years. Congress gave us that mandate when they established the IG Office. I think we have been successful. There is more work for us to do and with your support we can continue to be successful.

I have mentioned this morning that I have resource problems. I have funding problems. And I also have problems with not having enough law enforcement authority to do my job. I waste a lot of valuable time and so do my agents because we don't have the law enforcement authority to get the job done.

We have had subjects flee our country with ill-gotten gains because we didn't have the law enforcement authority to stop them. We have had evidence destroyed because we didn't have the law enforcement authority to stop that. I have had witnesses placed in danger. My special agents have been placed in danger all because we don't have the law enforcement authority to do the job.

Anything that this committee can do to help solve my problems and make my job easier so I can fight this battle would be appreciated.

Mr. SCHUMER. Thank you, Mr. Morey.

[The prepared statement of Mr. Morey follows:]

PREPARED STATEMENT OF LARRY D. MOREY, DEPUTY INSPECTOR
GENERAL FOR INVESTIGATIONS, OFFICE OF INSPECTOR GENERAL,
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Good morning Mr. Chairman and Members of the Subcommittee. I am Larry Morey, Deputy Inspector General of the Office of Inspector General (OIG). Thank you for the opportunity to testify on the subject of health care fraud in the Medicare program. We are pleased that the subcommittee is holding this hearing to discuss the important issue of health care fraud -- a problem that squanders our valuable resources and can adversely affect the health of our beneficiaries. At a time when health care reform is being debated, it is also appropriate that we address these issues to assure that our public health programs operate efficiently and effectively and that changes in our health care financing and delivery systems are made in a manner that minimizes the potential for fraud, waste, and abuse.

The rapid rise in expenditures and deficiencies in our health care delivery system has caused unprecedented attention and scrutiny in the health care area. This scrutiny has encompassed discussions regarding the magnitude and pervasiveness of fraud, waste, and abuse in our health care programs. As you know, the General Accounting Office (GAO) recently released a report entitled, *Health Insurance: Vulnerable Payers Lose Billions to Fraud and Abuse*. The report quotes experts in the health field who estimate the losses to fraud and abuse in health care is 10 percent, or approximately \$80 billion in 1992. We will discuss our experience in investigating Medicare and Medicaid fraud later in our testimony.

In discussing monetary losses to health programs, a distinction must be made between fraud, abuse, and waste. It is impossible to distinguish sharply between these terms since

frequently one problem involves all three. However, for purposes of rough definitions, we provide the following:

- **Fraud** is defined as the obtaining of something of value, through intentional misrepresentation or concealment of material facts.
- **Abuse** may be defined as any practice which is not consistent with the purpose of providing beneficiaries with medical services which are (1) medically necessary, (2) meet professionally recognized standards, and (3) fairly priced.
- **Waste** is the incurring of unnecessary costs as a result of deficient practices, systems, or controls.

Current Health Care Delivery

Before discussing the prevalence and detection of fraud and abuse in health programs, a brief overview of the current health care delivery system is appropriate. Currently, Americans are devoting more than 12 percent of our gross national product (GNP) to health care. Roughly three quarters of a trillion dollars were spent in this country on health care last year. This figure is expected to rise dramatically -- one projection indicates that health care expenditures could consume 31.5 percent of our GNP by the year 2020.

The Department of Health and Human Services (HHS) is the Federal Government's principal agency for promoting the health and welfare of Americans and providing essential human services to persons of every age group. The Department's two largest health programs are the Medicare and Medicaid programs, which are administered by the Health Care Financing Administration (HCFA). Medicare provides health insurance coverage to approximately 36

million beneficiaries aged 65 and older and to certain disabled individuals. The Medicaid program provides grants to States for medical care for more than 30 million low-income people. Expenditures for the Medicare program totalled \$140 billion in FY 1992 and expenditures for Medicaid totalled \$100 billion (\$72 billion federal share).

Fraud and Abuse Investigations

Created in 1976, the OIG is statutorily charged to protect the integrity of departmental programs, as well as promote their economy, efficiency and effectiveness. We meet our challenge through a comprehensive program of audits, inspections, program evaluations, and investigations. We are pleased with the accomplishments we have had in ensuring that beneficiaries receive quality care, that the integrity of the trust fund is maintained and that those individuals who defraud the Department's programs are held responsible for their actions.

Over the years, the OIG has proved that it is a sound investment. In FY 1992, the OIG generated savings, restitutions, penalties and interest of over \$61 for each Federal dollar invested in its operation. In FY 1992, we imposed 1,739 administrative sanctions on individuals and entities who defrauded or abused the Medicare and Medicaid programs or their beneficiaries. That is more than 44 times the level we reported in 1981. Successful health care prosecutions in the criminal courts have also dramatically increased, from 20 in 1982 to 168 in FY 1992. In fact, FY 1992 marked our 12th consecutive increase in successful prosecutions.

The OIG has always been innovative and active in investigating health care fraud. With 16 years of successful investigations in Medicare fraud, we have the most experience of any Federal agency in investigating health care fraud. We continue to share our knowledge in this complex field of health care fraud and abuse by providing training to such agencies as the FBI, among others. In fact, many of the health care cases in which the FBI is involved are jointly investigated with our office. I could not be more complimentary about how well we work together. The combined concentration of Federal and State investigators on geographic areas having a large volume of health care beneficiaries, has proved highly productive.

The OIG and the State Medicaid fraud control units (MFCUs), have concurrent investigative authority in the Medicaid program and conduct joint investigations. The MFCUs, supported largely (75-90 percent) by Federal dollars, devote over 1,000 MFCU personnel to investigating Medicaid fraud. Currently, Federal outlays for operation of the MFCUs are in excess of \$50 million. By contrast, the OIG is funded for only 110 investigators to investigate both the medicare and Medicaid programs, including the 11 states that do not have Medicaid fraud units. In summary, OIG has roughly 10 percent of the MFCU staff resources and slightly more than one-third the MFCU financial resources to cover its broader statutory mandate.

We also work closely with HCFA and the Medicare contractors that process Medicare claims and perform payment safeguard functions. As a result of our recommendations over the last

several years, HCFA initiated a broad effort to get the Medicare contractors to take a more active role in detecting, developing and referring potential fraud cases to the OIG. Among the changes that HCFA implemented was the creation of fraud units within most Medicare contractors. We believe that this will create a significant increase in quality case referrals to our office from the contractors. I also note that other law enforcement agencies continue to seek greater access to contractor data. Since, by statute, our agency is the only point of access for other law enforcement agencies, we believe we will be called on for assistance at a much greater rate than ever before.

Until recently, private health insurance programs had no significant investigative response to fraud. To address this issue, in 1985 we helped launch and were one of the founding members of the National Health Care Anti-Fraud Association (NHCAA). It is a consortium of our office, the Department of Justice (DOJ), FBI, MFCUs, private health insurers, and others who coordinate and share information and techniques for dealing with health care fraud. Our office has been on the board of directors since its inception. In addition to working on joint projects with this group, we help train the members in better detection techniques and alert them to new types of health fraud.

Prior to the inception of the NHCAA, private carriers did not have a means to share information in order to enhance the identification, prevention, detection, and prosecution of health care fraud. NHCAA was established on the premise that the diverse interests of health insurance reimbursement organizations, Blue Cross and Blue Shield organizations,

private corporations and Federal and State agencies and law enforcement operations could be channeled toward a common goal. The association currently consists of several hundred representatives from these types of organizations. NHCAA promotes information sharing among members (with appropriate legal safeguards), engages in public education on health care fraud issues, trains members and non-members through national and regional conferences, seminars, and workshops, and serves in an advisory capacity to industry, regulatory, and legislative bodies.

As an example of the complicated nature of health care fraud investigations, I would like to describe the activities of the Southern Ohio Health Care Task Force (SOHCTF). One of its primary objectives is to focus on fraud cases which are difficult to detect. The investigations involve the coordination of both the criminal and civil divisions of the United States Attorneys's Office. The task force began in October 1991 and is comprised of members of the United States Attorneys's Office for the Southern District of Ohio and special agents from the OIG, FBI, and the Postal Inspectors Office. Other agencies, such as the Railroad Retirement Board and CHAMPUS may also become involved on a case by case basis. The task force seeks to ensure that not only will all criminal prosecutions proceed quickly, but also that the appropriate civil remedies are instituted and that complete restitution is made to ensure the public that funds such as the Medicare trust fund, are restored for future generations. We try to prove the civil case, while simultaneously attacking the criminal aspect. The benefit of working a parallel investigation, in which civil and criminal case are being investigated concurrently is that many of the assets illegally obtained by the provider

can be confiscated and/or frozen, preventing the provider from disposing of them prior to criminal prosecution. The SOHCTF has 10 to 30 cases under investigation. To date, 12 cases have been favorably resolved by the SOHCTF.

Medicare and Medicaid Fraud and Abuse Vulnerabilities

Fraud is invisible until detected. Because of that fact, it is extremely difficult to estimate the total monetary loss as a result of fraud in the health care industry. While we cannot assign a dollar figure to the monetary loss to the Medicare and Medicaid programs as a result of fraud, we can tell you that we have noticed a dramatic increase in our investigative workload. Part of this is the result of the ever expanding size of these programs. Another part is due to the increase in administrative and prosecutable authorities that the Congress has enacted. It may also be the result of an increase in fraud.

In the 1970s, we found that we were dealing with individual provider fraud which involved relatively uncomplicated schemes, such as filing a false claim and resulted in a few thousand dollars of damage to the Medicare program. Today, however, instead of schemes which involve only one person or entity, it is now common to see cases involving groups of people who are intent on defrauding the Government. These schemes are perpetrated in a far more complex environment and often involve the use of sophisticated computer techniques and complicated business arrangements. These crimes frequently result in tens of millions of dollars in losses to Medicare and Medicaid, as well as other public and private health insurance programs.

Because of the limited time we have today, we have selected a few examples of fraudulent and abusive practices that will give you a broad overview of our office's investigations. Many of these areas merit further attention and corrective action -- whether administrative or legislative. A listing of our significant unimplemented monetary recommendations can be found in our *Cost Savers Handbook*, referred to as the *Red Book*. A listing of our significant unimplemented nonmonetary findings can be found in our *Program and Management Improvement Recommendations* referred to as the *Orange Book*.

Inaccurate Claims -- The Medicare program loses money when providers submit inaccurate claims that do not reflect the services actually performed or the supplies actually delivered. Gaming can take the form of unbundling and upcoding. Unbundling occurs when providers inflate charges far above the appropriate level by billing for the subcomponent parts of an item or service rather than the complete item or service. Upcoding is the practice of billing for a more intensive service than the one actually delivered.

Kickbacks -- Physician ownership of and compensation from entities to which they make referrals is a practice that has increased considerably in the last 10 years. Since 1987, we have received more than 1,569 allegations of violations of the anti-kickback statute, and have opened over 1,012 cases. Over 635 convictions, settlements, and exclusions have been obtained as a result of our investigations, as well as almost \$18.2 million in monetary recoveries. Research continues to determine the extent to which increased costs are a problem for other items and services that these joint ventures furnish.

Home Health Agency Fraud -- Home health agencies (HHA) provide care in the patient's home, with limited supervision by the attending physician. There are several categories of fraud which we have seen in HHA operations: cost report fraud; excessive services or services not rendered; use of unlicensed or untrained staff; falsified plans of care and forged physician's signatures; kickbacks; and intermediary hopping. Since 1986, we have concluded

24 successful criminal prosecutions of HHAs and their employees. Since 1991, we have excluded 15 HHAs, owners or employees from participating in Medicare.

Psychiatric Clinics -- Fraud involving psychiatric clinics can take many forms. In a scheme we have seen recently, hospitals pay physicians up to \$2,000 for the referral of patients to the facility. The amount of money is dependent on the number of patients referred to the hospital by the doctors. The payments to the doctors by the hospital are included as part of the costs incurred by the hospital on the cost reports that are submitted to Medicare. The payments received by the doctors are ostensibly for the writing of patient care manuals that will be utilized by the hospital in its care of the patients, but these manuals are never written. Services for both inpatients and outpatients are not rendered by the hospitals. In some instances, when the Medicare benefits run out for a particular diagnosis, the patient is re-diagnosed to ensure Medicare or Medicaid coverage.

Durable Medical Equipment (DME) -- For many years, we have issued reports documenting fraudulent, abusive and wasteful practices in the DME area. These deficiencies include questionable marketing techniques, inflated charges, and manipulation of loopholes in the law. In the last 3 years alone, over 80 convictions have been obtained in this area. We are pleased that the Department is currently undertaking reforms which will change point-of-sale rules and how provider numbers are issued. However, we believe that additional corrective action should be taken.

Laboratory Fraud -- We have encountered a number of schemes in the laboratory industry: (1) billing for services never rendered, (2) unauthorized or excessive tests, and (3) disguising billing procedures in which the carrier is actually billed twice. In the last 5 years, almost 50 convictions and civil actions have been obtained as a result of our laboratory investigations.

Medicare Secondary Payer Activities -- Medicare is the secondary payer to certain employer health plans for beneficiaries age 65 and older, disabled beneficiaries, and during the first 18 months of a beneficiary's entitlement to Medicare on the basis of end stage renal disease (ESRD). Noncompliance with the MSP statute has been documented for years and our office has issued numerous reports on this subject. Both administrative and legislative

action has been taken to correct the problem. However, losses continue and as of September 1992, HCFA reported about \$961.6 million in past MSP payments that had not been collected. Therefore, we believe that additional corrective action is required to recover payments that have been inappropriately paid by the Government and to prevent future losses.

Hospital Credit Balances -- The OIG has documented that the Medicare program loses millions of dollars because Medicare credit balances are not returned to the Government (about \$266 million when we conducted our report). Credit balances occur because (1) Medicare is billed twice, (2) services are reimbursed by another insurer as well as Medicare and (3) services are billed but never rendered. While credit balances are an overpayment and monies should be recouped by the Government, in some instances we believe that fraud has been perpetrated. We are currently investigating certain facilities to determine whether criminal prosecution is warranted.

As I have previously stated, there are no clear lines of distinction among the many types of fraud we investigate. As an example of a cross-cutting case involving laboratory fraud, kickbacks, and upcoding, I want to describe our recent settlement with the National Health Laboratories, Inc. (NHL). The NHL is a major blood testing laboratory headquartered in California which pled guilty to submitting false claims to the Government and agreed to pay \$100 million in a global civil settlement for defrauding Medicare by manipulating doctors into ordering medically unnecessary tests. The settlement is the largest ever reached between the Government and a health care provider in a health care fraud case. The NHL also will pay a criminal fine of \$1 million and reimburse State Medicaid agencies \$10 million for their losses attributable to criminal conduct. The president and chief executive officer of NHL also pled guilty and will forfeit \$500,000. The agreement settles claims that NHL added

high density lipoprotein cholesterol tests and iron storage tests to the series of blood tests doctors order most. This series of tests is most used because it is highly informative and relatively low-cost. By 1989, NHL was performing about 7 million of these tests a year. The two extra tests, however, were not really part of the series run, and were billed separately to Medicare regardless of whether the doctors had ordered them. The OIG agents conducted interviews and investigations throughout the country and determined the magnitude of the fraud during the course of the 3 year investigation. Through NHL's scheme, the company knowingly submitted a large number of false claims for payment from 1987 to the present.

Other Reforms Needed

As policy makers consider ways to reform the health care system, lessons drawn from the Medicare program and its vulnerability to fraud, waste, and abuse can be instructive. We believe that there are four categories of deficiencies in the Medicare program: (1) some payments are excessive, (2) unnecessary and inappropriate care is rendered to beneficiaries, (3) financial conflicts of interest exist, and (4) Medicare systems are vulnerable to manipulation.

In response to these concerns, an Interagency Task Force on Health Care Anti-Fraud, Abuse and Waste has recently issued a variety of proposals designed to reduce the level of fraud, waste, and abuse in Medicare and other health insurance programs. These proposals include the following:

- The current Medicare-Medicaid prohibition on kickbacks should be extended to all public and private payers.
- The current Medicare ban on payments for self-referrals should be expanded to additional services where the physician does not directly render the service and where abuses have been identified.
- The Medicare-Medicaid civil monetary penalty statutes and the Quality of Care sanctions should be strengthened to deter abuses.
- The routine waiver of Medicare Part B coinsurance except for low-income beneficiaries should be explicitly prohibited.
- Databases of all final adverse actions and certain active fraud investigations against health care practitioners should be established with appropriate safeguards for privacy and access.
- Require the development and adoption of standards to incorporate accountability into the electronic media claims process. This would include provisions to ensure that the identity of the individual that caused the transmission of the claim is known, the assumption of responsibility by providers for the accuracy of claims submitted on their behalf, and the patient is provided with verification of the type of services rendered.

Conclusion

The types of fraud that I have discussed in my testimony today could be avoided or lessened by closing loopholes that exist in the law or in Medicare rules and regulations. Hearings such as this, help draw attention to these important problems that confront and weaken our health care delivery system. This concludes my prepared testimony. I shall be happy to answer any questions you may have.

Mr. SCHUMER. Ms. Shikles.

STATEMENT OF JANET L. SHIKLES, DIRECTOR, HEALTH FINANCING AND POLICY ISSUES, HUMAN RESOURCES DIVISION, U.S. GENERAL ACCOUNTING OFFICE

Ms. SHIKLES. Thank you, Mr. Chairman and members of the committee. I also appreciate the opportunity to testify today on health care fraud and abuse and the need for better remedies and more resources to combat the problem.

Recently, the GAO issued a series of high risk reports on Federal programs and included Medicare fraud which we think is serious.

Last May we cited a report that estimated that fraud and abuse adds 10 percent to our Nation's health care costs which this year may run at about \$900 billion. The magnitude of this loss stems from several problems in the health insurance system that allow unscrupulous health care providers to cheat health insurance companies and programs out of billions annually.

The fraud scheme, the rolling lab scheme that you heard about from your first panel, illustrates vulnerabilities of the system. As you cited, Mr. Chairman, this scam billed about \$1 billion to all insurers in California. What is interesting about this case is that it actually has been going on since the early 1980's. At the time it enlisted 200 physicians and other providers, basically getting the providers by advertising in the Los Angeles Times.

What is concerning is the outcome so far. Even though Medicare and private insurers have invested a lot of resources in trying to nail these guys, getting a judgment of about \$18 million, very little of this money has been recovered.

The other concern about a case this large is that it means that it has taken up a lot of investigative and prosecutorial resources which means that other scams can't be investigated. California officials told us they are aware of six other scams just like the rolling lab scam going on in southern California. They won't be able to take this one on until they take the rolling lab scam to trial.

Just to let you know these were current scams, one of my staff this past year working on this particular case went home one night and got a phone call from a similar scam operator soliciting her to come in for a series of tests.

Our concern about the resources—

Mr. SCHUMER. Did you tell her to go? Another Dr. Marr.

Ms. SHIKLES. They lost interest when she told them she was in an HMO. They just go after fee-for-service providers.

What this illustrates is the kind of resources required and the fact that the resources we have available with the Department of Justice or IG Office, two agencies charged with investigating fraud and abuse, is particularly concerning. It is particularly concerning for the Medicare program because the contractors which process claims and are charged with identifying fraud and abuse, and there are about 80 located around the country, depend very strongly on the IG's Office. Once they identify the cases or problems, they refer them to the Inspector General's Office. If the contractor knows that the IG is so backed up and doesn't have enough resources to investigate these cases, there is no point in referring them. You just go after a smaller payment. We are losing millions of dollars because

of this. We have found small cases involving as little as \$700 that, when properly investigated have identified over \$1 million in Medicare losses.

In summary, we believe at present that only a fraction of the fraud and abuse currently being committed against the health care system is being identified and prosecuted. And, without adequate resources, effective investigation and pursuit of health care fraud is not possible.

We think that you can't just put more resources in the area. There is also some systemic problems in the way our system is organized that we would like to draw the committee's attention to. These have to do with a set of things that you saw in the rolling labs case but you see in any health care fraud activity that is going on.

One of them has to do with the fact that we have no standardization in our system so we have about 1,200 public and private payers paying about 4 billion claims a year to hundreds of thousands of providers all using different forms and different billing procedures. What this means is if you are a fraudulent provider—and you heard this from your first panel—it is not tough to game the system. You split the bills, make sure they are spread over different insurers, and it is difficult for the insurers to follow them up, or for a sophisticated system to put that back together again.

Another problem has to do with the fact that insurers can't collaborate. This has to do with privacy issues and antitrust issues. In the rolling labs case, Medicare actually caught on to the scam very early and got the doctors out of the system. But the fraudsters didn't miss a beat. They moved over and started billing other insurers. That is what you see in other scams.

Another concern has to do with what is happening to health care. Health care is moving out of an inpatient setting to the outpatient setting. You are seeing surgery, radiation treatment, emergency care, all being provided in an outpatient setting. But, increasingly, this is provided in freestanding, unregulated, unlicensed facilities. It is very difficult for insurers to know whether they are being billed by a reputable service that is providing legitimate services or a scam operation like rolling labs, unlisted and unregulated.

Finally, successful prosecutions, as you have seen, often don't end up in recoveries to the private insurers. Thus, there is not much incentive, even for Medicare, to invest a lot of effort in going after these guys, for example, In the rolling labs case, the physicians are still practicing in California and it has been nearly 10 years since the scam was first identified.

Because of these issues we have recommended to Congress that it consider establishing a fraud commission. This would be made up of representatives from public and private payers, providers and Federal and State law enforcement officials and the IG's Office. We believe there is a set of systemic issues that need to be addressed that have nothing to do with how you reform the health care system that you could look at. These would include standardization of billing, greater regulation of outpatient facilities and other issues. We have recommended that this commission would be addressing these issues and other key issues and come to agreement and present recommendations to Congress.

Mr. Chairman, thank you.

[The prepared statement of Ms. Shikles follows:]

PREPARED STATEMENT OF JANET L. SHIKLES, DIRECTOR, HEALTH
FINANCING AND POLICY ISSUES, HUMAN RESOURCES DIVISION,
U.S. GENERAL ACCOUNTING OFFICE

SUMMARY

The size of the health care sector and sheer volume of money involved make it an attractive target for fraud and abuse. Health insurance experts estimate that fraud and abuse contribute to some 10 percent of the \$800-plus billion currently spent on health care. Relative to the magnitude of the problem, GAO believes that resources devoted to combatting health insurance fraud are small.

Profiteers are able to stay ahead of those who pay claims, in part, because of the obstacles to preventing and pursuing dishonest practices. These practices include overcharging for services provided, charging for services not rendered, accepting bribes or kickbacks for referring patients, and rendering inappropriate or unnecessary services. Insurers have difficulty discerning wrongful acts amidst the multiple activities that take place at the time of processing claims. Furthermore, collaboration on fraud case development among industry members is limited due to concerns over violating privacy and antitrust laws.

Once detected, moreover, fraud is expensive and time-consuming to pursue both criminally and civilly; even convictions often do not result in the recovery of losses. In particular, limited resources can constrain state and federal prosecutors from pursuing health care cases involving relatively small dollar amounts. In several jurisdictions, for example, federal prosecutors said they generally accept only criminal health care cases that are clear-cut and involve \$100,000 or more, because caseloads for such crimes as savings and loan fraud and drug-trafficking consume substantial prosecutorial resources.

Two federal agencies significantly involved in pursuing health care fraud are the Department of Justice and the Office of the Inspector General in the Department of Health and Human Services (HHS). Both cite limited resources as a problem. The number of Inspector General investigators has declined over the last 5 years, while the Inspector General's statutory responsibilities and the size and complexity of the federal programs that the Inspector General investigates have increased significantly. Without adequate resources, effective investigation and pursuit of health care fraud is not possible.

Added resources alone, however, will not succeed in overcoming fraud and abuse in the health insurance industry. Structural issues such as limitations on information-sharing among insurers and incompatible data systems hamper efforts to detect the providers' aberrant billing patterns. Because of the complexity involved in remedying these problems, GAO asked the Congress to consider establishing a national commission to develop comprehensive solutions to health insurance fraud and abuse.

Dear Mr. Chairman:

I appreciate the opportunity to testify today on health care fraud and abuse and the need for better remedies and more resources to combat the problem. Recently we reported on such federal programs as Medicare that are at risk of substantial losses to waste, fraud, and abuse.¹ We have also, over the past year, issued several other reports addressing aspects of health care fraud and abuse. Essentially, our work has shown that (1) all health care payers are vulnerable to fraud and abuse, (2) significant obstacles hinder the prevention of dishonest billing practices and the pursuit of health care profiteers, and (3) the resources devoted to detection and prosecution are not adequate.

Now I would like to discuss these issues in greater detail. First I will address the size and nature of health insurance fraud and abuse, followed by resource and other problems associated with investigation and prosecution.

HEALTH INSURANCE FRAUD AND ABUSE

Last May, we issued a report citing an estimate that fraud and abuse adds some 10 percent to U.S. health care's current costs,²

¹Medicare Claims (GAO/HR-93-6, December 1992).

²Health Insurance: Vulnerable Payers Lose Billions to Fraud and Abuse (GAO/HRD-92-69, May 7, 1992).

which currently exceed \$800 billion. We would like to reiterate that this estimate, although often cited by health experts, is uncertain because of the hidden nature of fraudulent and abusive practices.

The magnitude of this loss stems from several problems in the health insurance system that allow unscrupulous health care providers to cheat health insurance companies and programs out of billions of dollars annually. The problems do not fall into mutually exclusive categories, but in general they include the following:

- Health insurers operate independently and are constrained legally and administratively from collaborating on efforts to confront fraudulent providers. Ultimately, even when fraudulent providers get caught by one insurer, they can continue billing other insurers.
- Criminal prosecution and civil pursuit of fraud is expensive, slow, and has been shown to have little chance of recovering financial losses. Moreover, private insurers are largely without access to the administrative remedies of the public payers, such as the ability to exclude providers convicted of health care fraud from billing the public programs.

-- Insurance and law enforcement resources are not sufficient to detect and pursue health care fraud effectively.

The vulnerability of the health care system to fraud is illustrated by a California scheme that has resulted in the loss of millions of dollars. The case is alleged to have involved over \$1 billion in fraudulent billings from as many as 200 physicians and other providers. This scheme centered around getting people with health insurance to go to mobile labs, called "rolling labs," that did noninvasive tests, such as heart and blood-pressure measurements. Frequently, the labs and the referring physicians used phony diagnoses in submitting the insurance claims.

Thus far, the outcome of this scheme is that the owners have been both sued and prosecuted successfully, yet virtually no monies have been recovered. Also, at least six similar schemes are known to be operating in southern California. Schemes of this nature highlight several serious problems facing public and private payers. First, large financial losses to the health care system can occur as a result of even a single scheme. Second, fraudulent providers can bill insurers with relative ease. And third, efforts to investigate, prosecute, and recover losses from those involved in the schemes are time-consuming and costly.

Next, I will focus on the problems of investigating and prosecuting health insurance fraud.

PROBLEMS INVESTIGATING AND PROSECUTING HEALTHINSURANCE FRAUD AND ABUSE

Insurers face significant legal hurdles and expense in investigating, prosecuting, and recovering losses from fraudulent or abusive providers. Investigative and prosecutorial resources and priorities vary by jurisdiction, often constraining state and federal prosecutors from pursuing health care cases involving relatively small dollar amounts. In several jurisdictions, for example, federal prosecutors told us that they generally accept only criminal health care cases that are clear-cut and involve \$100,000 or more, because caseloads for such crimes as savings and loan fraud and drug-trafficking consume substantial prosecutorial resources. An official from a large insurance company with an active fraud detection program told us that only about 1 percent of all cases referred to federal prosecutors were accepted.

An irony of the criminal prosecution approach is that a single large fraud case can consume significant investigative and prosecutorial resources, leaving other cases unpursued. For example, in the case of the rolling labs scheme, California state investigators told us that similar schemes allegedly operating in the same geographic area were not likely to be investigated or prosecuted until the rolling labs case had gone to trial.

The lack of investigative resources has constrained two federal agencies significantly involved in pursuing health care fraud--the Department of Justice and the Office of the Inspector General in the Department of Health and Human Services (HHS).

At least until recently, Department of Justice efforts to combat health insurance fraud have been adversely affected by resource constraints. Recognizing the need for additional resources to address health care fraud, the Federal Bureau of Investigation (FBI) reassigned 50 agents from other areas to health care. This means that a total of 150 agents nationwide will be devoted to health care cases. At the same time, the Department of Justice assigned 10 new positions to enforce a health care fraud initiative and formed a health care fraud unit within its criminal division.

The HHS Inspector General continues to cite resource limitations as a major impediment to investigating and pursuing many types of fraud and abuse. For example, the number of Inspector General investigators has declined during the last 5 years, though the Inspector General's statutory responsibilities, and the size and complexity of the federal programs that the Inspector General investigates has increased significantly. What this means is that in many localities the Inspector General has few people to investigate health insurance fraud. For example, until recently, the Inspector General had less than two full-time people

working on health fraud in southern California, where rolling-labs schemes have been prevalent.

Such investigative resource limitations can discourage Medicare claims processors--involving some 80 contractors across the country--from developing cases to refer for further action. That is, the contractors depend on the Inspector General to pursue fraud cases, and when contractors anticipate that few cases will be accepted for further investigation, they have little incentive to develop any but the most egregious cases for referral.

One GAO study that examined how Medicare contractors review complaints they receive alleging fraud illustrates the potential cost of not pursuing these leads. Beneficiary complaints of provider fraud and abuse are Medicare's first line of defense against misspent program dollars. Inadequate investigation of these complaints can result in missed opportunities to recover overpayments and to send a message that fraudulent or abusive behavior will not be tolerated.³

In fiscal year 1990, Medicare contractors reported receiving about 18 million calls--most of which were from program beneficiaries. In our review of calls at five contractors, however, we found over half of the complaints that involved

Medicare: Improper Handling of Beneficiary Complaints of Provider Fraud and Abuse (GAO/HRD-92-1, Oct. 2, 1991).

allegations of fraud or abuse were not referred to contractor investigative staff. Not all complaints that were properly referred, moreover, were adequately investigated.

The importance of investigating complaints is illustrated by a recent case against a national laboratory. The laboratory led doctors to believe it could perform additional tests, though medically unnecessary, at little or no cost when doctors ordered a routine battery of chemistry tests on a blood specimen. In fact, when billing Medicare, the laboratory filed claims for the full price of the additional tests. The doctors were unaware of how the laboratory represented its charges to Medicare because the laboratory submitted its claims directly to Medicare. This problem had been ongoing since 1987 and resulted in big payment increases to the laboratory for certain tests. The HHS Office of the Inspector General became aware of the scheme after the laboratory's competitors advised the Office of the lower prices the national laboratory charged doctors compared to what it charged Medicare. The competitors' complaints led to a grand jury investigation in 1990. In December 1992, the laboratory pleaded guilty to submitting false claims to the government and agreed to repay more than \$110 million in civil settlements and criminal fines.

CONCLUDING OBSERVATIONS

Only a fraction of the fraud and abuse committed against the health care system is identified and prosecuted and that which has been detected has involved substantial sums. Without adequate resources, effective investigation and pursuit of health care fraud is not possible. Currently, dishonest providers can continue operating, in part, because of the lack of staff and money dedicated to pursuing them.

However, added resources alone will not succeed in overcoming fraud and abuse in the health insurance industry. We believe that the efforts of independent private payers, public payers, and state insurance and licensing agencies as well as state and federal law enforcement agencies need to be better coordinated to conduct a more fruitful attack on health care fraud.

In addition, as we discussed in our May 1992 report cited earlier, structural issues, such as limitations on information-sharing among insurers and incompatible data systems, allow unscrupulous providers to move from one insurer to another. The complex issues involved in developing remedies present a dilemma to policymakers: on the one hand, safeguards must be adequate for prevention, detection, and pursuit; on the other, they must not be unduly burdensome or intrusive for policyholders, providers, insurers, and law enforcement officials.

A national commission, composed of diverse members with balanced viewpoints, could foster communication and identify ways to address obstacles that prevent the efficient pursuit of fraud and abuse. Therefore, we have previously recommended that the Congress consider establishing a national health care fraud commission composed of private and public payers, providers, and law enforcement agencies. Such a commission would be best suited to weighing such important trade-offs as greater information-sharing among insurers vs. concerns over privacy and antitrust issues and greater regulation of provider ownership arrangements vs. concerns about restraint on competition. The commission could also be responsible for developing recommendations addressing (1) how insurers can coordinate case development and prosecution efforts, (2) whether and how to regulate unlicensed medical facilities, and (3) how insurers can standardize claims information and billing rules.

* * * *

Mr. Chairman, this concludes my testimony. I'd be pleased to answer any questions.

Mr. SCHUMER. I want to thank each of you for your very excellent testimony.

Mr. Potts, is it likely that people will go to jail in the rolling labs case that Dr. Marr has been so prominent in and will testify for?

Mr. POTTS. Mr. Chairman, we were not in that investigation so I would defer that to others, but I would hope, based on the amount that you are dealing with, that some of them would go to jail.

Mr. SCHUMER. OK.

Mr. POTTS. We did not take part in that investigation.

Mr. SCHUMER. OK. Let me ask a question of all of you. I take it everyone agrees that if we put more resources into Mr. Potts' operation, Mr. Morey's operation and others, that we would actually make money after a few years. Is that correct?

Ms. SHIKLES. That is correct.

Mr. MOREY. Yes.

Mr. POTTS. Yes.

Mr. SCHUMER. Are the criminal laws tough enough? Do you have all the legal tools you need except for resources?

Mr. POTTS. We would like additional legislative resources certainly. The Federal Medicare-Medicaid antikickback statute, title 42, has been a great tool for us because it makes it a felony to knowingly offer or to receive any remuneration for any type of referral of patients or purchase of a product where you try to get payments out of Medicare or Medicaid. That is a tremendous tool, but it doesn't even apply to all the Federal programs, doesn't apply to CHAMPUS, not to the private insurers.

So you can have that type of what is, essentially, a kickback in the private insurance side, and we can't go after it with that same type of backing.

Mr. SCHUMER. I would ask you, Mr. Potts and the Department, to submit to us in writing, not part of this record necessarily, all the strengthenings of the law, aside from resources, that you would like to see.

Mr. POTTS. And forfeiture is another area.

Mr. SCHUMER. It is utterly appalling. It amazes me that in this rolling labs scheme nobody has yet been brought to justice. The amount of money we recover is not enough.

Mr. Potts, you have 56 field offices. I believe you mentioned you have 150 agents devoted to health care fraud, 3 for each office. In your estimation, how many agents in the average field office would it take to adequately investigate health care fraud?

Mr. POTTS. We have estimated—we have never been given resources for the health care fraud. All the 150 we have come from other places.

Mr. SCHUMER. Right.

Mr. POTTS. We have estimated we need about an additional 300 agents across the Nation in order to adequately investigate health care fraud.

Mr. SCHUMER. How much money could you get back? In the S&L fraud cases, we found that it was not possible to get much money back. Is it the same here?

Mr. POTTS. We are certainly seeing some of that here, also, in terms of some of the money being gone. An example is a rather in-

credible case in New York where it is hard to find any good guys in the case at all. The victims are all of us in terms of what we are paying. But you had the clinics set up where there was no—there were no doctors. They were physicians assistants or people off the street so they were billing for exams that shouldn't be conducted by these people. They were taking blood from these folks and sending it to labs that were pouring it down the sink and sending reports back and charging for that.

The people who were getting drugs—it was essentially a blood-for-pills scheme. They came in and gave blood, and they sent that off for testing, and they give them prescriptions for medicine which they could take out and sell to diverters. It is hard to find any good folks there, and you are looking at about an \$8 million loss to Medicaid, and we are trying to find some of that money. It is tough to find any assets.

The assets in terms of the clinics themselves were pretty much storefronts that had deplorable sanitary conditions. They had no running water. So even if we take those we are not getting a lot back for the Government.

On the other hand, we have had considerable success with the Goldpill investigation, a case in Dublin, GA, where it took a minimal amount of money to investigate the case and to prosecute the case and we get \$1.9 million back.

I think we have been able to show a four-to-one return on these kind of white-collar crime cases.

Mr. SCHUMER. Mr. Morey, you mentioned that you have one field agent for every 8,700 providers. At that rate, I take it—I just did a little math—it would take, if they spent 1 day on each provider, it would take you 40 years to examine every provider. That is unbelievable.

You also mentioned that you hit many providers with administrative sanctions, but you couldn't get to them in the criminal area. They should have gotten criminal sanctions, I presume. Do you believe those cases merit criminal sanctions?

Mr. MOREY. Yes, I do.

Mr. SCHUMER. What is preventing that from happening?

Mr. MOREY. Congress has been fairly good to the Office of the IG. When I got there we had maybe 20 administrative sanction provisions. Well, that number has now grown to 80. The first 20 I thought were really fraud oriented. The last 60 are all compliance forcing a health care provider to do what they should be doing to be honest. We have now used the IG in a compliance setting. Just make them comply with it, which seems really wrong and throws me into a completely different framework.

When we look at those 1,700, that is truly amazing. One time we had 30 a year. Now I am looking at 1,700—1,739 to be exact. We currently have about 7,000 health care providers out of our program, some out for 5 years, some out for life or 25 years. That is a whole lot of health care providers out of our program.

Mr. SCHUMER. I appreciate your being so frank about how understaffed you are. That is the only way we can get help. Maybe it is during the synapses in administrations that we can get honest answers.

One of the problems with health care fraud, of course, is that insurance is a third-party payer system so the consumer doesn't have an incentive to deal with fraud. However, I get some people in my office. They are afraid. They call up and say, I was billed for this. I know I didn't receive the treatments for which my insurance company was billed.

One elderly gentleman told me—he is 82—that he was billed for a protoscope he had never received. Now, I think I would know if I had gotten a proctoscope. My people don't mince words like you don't, Mr. Morey. But they are afraid because they have a personal relationship with the physician that they don't want to jeopardize.

Then you have people who just don't know. And you have people who don't care. Has there been a great deal of success with the 800 numbers in getting the consumer to help monitor the kind of fraud we have or is that an impossible goal?

Mr. MOREY. No. I think, actually, if you took a look at where I get most of my cases are from carriers who refer the cases to us. The second is from the American public. And over a period of 10 years I've learned they do call in, and they are becoming concerned about these increased expenses.

Mr. SCHUMER. Do you find that concern increasing as health care costs go through the roof?

Mr. MOREY. Yes.

Mr. POTTS. Yes, sir.

Ms. SHIKLES. Yes, in Medicare we did a study a year ago, from the beneficiaries' perspective, they make 18 million calls a year to the contractors or carriers, and our staff listened in to about a thousand of the calls and everyone was surprised at how angry the beneficiaries are. They are scrutinizing the bills and calling in and saying, I didn't see this doctor. I didn't get this test. What is going on?

Afterwards, they write letters. Unfortunately, what we found in that report was that the contractors then were not investigating the cases, not given the right information, and not following up on what turns out to be good fraud referrals. But the public is mad and is writing in.

Mr. SCHUMER. Is it productive here to beef up rewards for the public to report fraud? Do people think yes or no? Is that a productive approach?

Mr. MOREY. I think yes, especially on our beneficiaries. We show a number that if they question anything that they should get back with the carrier, and the carrier is supposed to develop their claim.

Mr. SCHUMER. OK. I have more questions, but my time is up.

Let me go to my colleague from New Mexico. But first I want to welcome another new member of this subcommittee, someone who has a great deal of experience on the full committee and is respected tremendously on many of the issues we cover, Don Edwards.

Mr. EDWARDS. Thank you.

Mr. SCHUMER. Mr. Schiff.

Mr. SCHIFF. Mr. Chairman, I have one question for the entire panel.

I want to point out, as you gathered from our remarks, you know we are all equally interested in doing what we can do to suppress fraud. We see the damage it does to everyone. And you can see—you can expect us to work together on a personal and bipartisan basis to take such action as we can.

With that in mind, I would like to ask each of you, if you had a magic wand—all of us collectively had the magic wand. We have other colleagues, other issues in Congress as a whole. But if you had the magic wand and said this is what we want from Congress. I wonder if each of you could give us one, two, perhaps three things of what would help—resources, changes in the law? Or, what would be best to help you do your job?

I wonder if I might start with Mr. Potts first.

Mr. POTTS. I think I would ask you to use that as quickly as you could to change some—give us additional legislation on the Anti-Kickback Act and additional forfeiture provisions within the Anti-Kickback Act as well as mail fraud and wire fraud. I think it is important that we have the forfeiture provisions applied in a judicious and careful way, but they have to apply to white-collar crime cases. They should not be able to get away with these incredible profits they walk away from these schemes with.

Clearly, I think there is a need for additional resources. Resources are not the only answer. You could throw thousands of people at this problem and keep them all quite busy. We have to be able to target the right areas and get the major scams, but resources are clearly needed across the board.

Mr. SCHIFF. On the issue—before the next witness—on the issue of legislation, I wonder if you would get together with the Justice Department and draft those changes to the act that you would like to see enacted and provide them to the members of the subcommittee?

Mr. POTTS. Yes, sir. We would be happy to do that.

Mr. SCHIFF. Mr. Morey, same question.

Mr. MOREY. My biggest concern is resources. I think if I were able to double my resources, talking about the funding and the investigators, that I would quadruple my output. I could do a better job. And I basically feel we have the legislation in title 42 or title 18 to get the job done. There are minor changes that might be helpful but, basically, ours is a resource problem.

Mr. SCHIFF. If you have specific suggestions from your agency that would improve the law, would you draft them and submit them to the members of the subcommittee? That would be great.

Mr. MOREY. Yes, of course.

[The information follows:]



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Washington, D.C. 20201

FEB 5 1993

The Honorable Charles E. Schumer
Chairman
Subcommittee on Crime and Criminal
Justice
Committee on the Judiciary
Washington, D.C. 20515

Dear Mr. Schumer:

We very much enjoyed the opportunity to testify before your subcommittee yesterday concerning critical issues involving investigation and prosecution of health care fraud. At the close of that hearing, you asked that we provide you with more specific information concerning various areas where our continued successful prevention and detection of such fraud by the Office of Inspector General of the Department of Health and Human Services could be more efficient and effective. Following is the information you requested:

Civil Monetary Penalty Statute - Section 1128A of the Social Security Act provides for the imposition of civil monetary penalties and exclusions for numerous types of fraud and abuse related to Medicare and State health care programs. Currently, the statute provides for a penalty of up to \$2,000 for each item or service at issue, and an assessment of not more than twice the amount claimed. At the time that the statute was enacted, these amounts paralleled the penalties in the Civil False Claims Act (31 U.S.C. § 3729). However, in 1986, the penalties in the False Claims Act were increased to a maximum of \$10,000 per item or service claimed, and the assessment to treble the amount claimed. To date, there has been no corresponding increase in the penalties under the Civil Monetary Penalties law.

Forfeiture of Proceeds of Health Care Fraud - Under current Federal law, it is a criminal offense to defraud the United States, to make false statements to the Government, or to file false claims for payment by the Government. Moreover, it is a Federal offense to defraud private individuals or businesses for the purposes of obtaining money or property, if the mails or wires are used for the purpose of executing the scheme. Currently, however, there is no forfeiture remedy available to the United States for fraud offenses in general, or health care fraud in particular. Forfeiture of the proceeds of health care fraud would provide a substantial deterrent effect, and would better ensure that the United States recovers funds obtained pursuant to fraudulent health care practices. Moreover, the proceeds

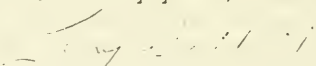
from successful asset forfeitures could be used to support future health care investigations by the Federal Bureau of Investigation, the Office of Inspector General, and others.

Uniform Law Enforcement Authorities - Under current law, agents of the Office of Inspector General of the Department of Health and Human Services may only perform certain law enforcement functions when they are authorized to do so pursuant to designations as Special Deputy United States Marshals. These functions are: to seek and execute search and arrest warrants relating to offenses within the jurisdiction of the Inspector General, to effect arrests without a warrant for violations within the jurisdiction of the Inspector General, and to carry a firearm in support of the above functions. Currently, over one-half of the criminal investigators within the Office of Inspector General are deputized for purposes of one or more cases. However, we are required to undergo a lengthy administrative process for securing deputation for each investigation.

Finally, you specifically asked for historical information concerning the level of funding for the Office of Inspector General. Our budget grew 34 percent between Fiscal Years 1987 and 1990, permitting us to hire new staff to keep pace with our growing responsibilities. Thereafter, in Fiscal Years 1990, 1991 and 1992, our appropriations were virtually constant and did not keep up with mandatory budget increases. Even the 4 percent increase in our Fiscal Year 1993 appropriation did not cover mandatory increases such as salaries and benefits. Thus, we have been forced to freeze all hiring since September 1992. The result has been a drop in staff "full-time equivalents" from 1,437 in 1991, to 1,330 in 1993. As a result, our Office of Investigations has reduced its law enforcement staff available to fight health care fraud by 17 percent. With these reductions, it will be difficult to provide effective oversight of rapidly increasing health care expenditures.

We hope that the above information is useful to you. We look forward to raising these and other issues with the new Administration, and to working with them, and you, to fulfill the Federal Government's grave responsibility to eliminate fraud in today's health care systems.

Sincerely yours,


Larry D. Morey
Deputy Inspector General
for Investigations

Mr. SCHIFF. With respect to resources, your point is for additional expenditures. You believe the total savings to the Government would more than offset the expenditures?

Mr. MOREY. Earlier in my testimony I think I quoted for every dollar you invest we give you back \$61. As a taxpayer, I think that is a wise investment on your part.

Mr. SCHIFF. Pretty good one.

Mr. SCHUMER. Let alone as a capitalist.

Mr. SCHIFF. Ms. Shikles, same question.

Ms. SHIKLES. I think I would focus on legislation that would address some of the conditions that allow fraud and abuse in our health care system to prosper. So a couple of those legislative actions I would say would be to require some type of standardization and one billing number per provider perhaps nationally.

You could take off from the work of Secretary Sullivan but, actually, that would go a long way toward cutting down some of this. In the rolling lab scam they had 600 different billing numbers, and you heard from the panel that, by using different billing numbers, the system just doesn't put it back together that it is coming from one address.

The second thing I would set up is a mechanism that insurers can use to report on fraud activities, without getting in trouble with potential privacy or antitrust violations. So that if Aetna catches somebody and gets rid of them they could report this to State insurance offices so that that office could alert all the other insurers about what is going on.

What you see now is that Medicare and Medicaid catches somebody, but the crooks don't miss a beat. They move on and start billing the other insurers.

Then I would take the ban in Medicare for self-referral to clinical labs and apply it to a whole set of procedures both publicly and privately. This is that physicians can refer patients to facilities where they have invested. And, if you look at fraud activities, there are always kickbacks and self-referral going on. If you had a self-referral ban this would help.

Finally, you have to look at figuring out who can bill public and private insurers. Do we want just anybody out of the back of their station wagon to be able to bill an insurer and the insurer has to pay? In many situations, this is what is going on?

Mr. SCHIFF. Certainly you didn't miss a beat either, I see.

I know this is perhaps something extra, GAO does not normally draft legislation.

Ms. SHIKLES. We could do that.

Mr. SCHIFF. If you can, perhaps in consultation with the Justice Department, I would ask that you submit any suggestions that you may have to members of the subcommittee.

Thank you, I yield back Mr. Chairman.

[The information follows:]



United States
General Accounting Office
Washington, D.C. 20548

Human Resources Division

March 8, 1993

The Honorable Charles E. Schumer
Chairman, Subcommittee on Crime
and Criminal Justice
362 Ford House Office Building

Dear Mr. Chairman:

During our testimony before your Subcommittee on January 4, 1993, Congressman Schiff asked that we submit suggestions for legislation that could help reduce the health care system's vulnerability to fraud and abuse. Our work over the past year has convinced us that a broad range of legislation may be required to address the underlying causes of this vulnerability.

In a report that we issued last year, Health Insurance: Vulnerable Payers Lose Billions to Fraud and Abuse, we identified a variety of factors that enhance profiteers' ability to stay ahead of insurers. These include (1) the independent operations of the various health insurers that limit collaborative efforts to confront fraudulent providers, (2) growing financial ties between health care facilities and the practitioners who control referrals to those facilities, (3) the movement of many health services from regulated facilities, such as hospitals, to nonregulated and oftentimes unlicensed freestanding facilities, and (4) the costs associated with legal and administrative remedies to fraud and abuse.

Diverse and autonomous insurers have few established means of collaborating systematically to solve fraud and abuse problems. In our view, if the efforts of independent payers, public payers, and state insurance and licensing agencies, as well as state and federal law enforcement agencies, were more coordinated, the attack on health care fraud and abuse would be more fruitful. Therefore, in 1992 we asked the Congress to consider establishing a national health care fraud commission to develop recommendations on issues such as:

- Developing greater standardization of claims formats to facilitate fraud detection and prevention.

- Establishing mechanisms to allow the exchange of information without undermining legitimate patient and provider privacy concerns or violating antitrust considerations.
- Assessing the need to regulate new provider types and develop criteria for physician referrals to facilities where physicians have a financial interest.
- Creating model state statutes that establish state insurance fraud units and strengthen insurers' ability to pursue and recover from fraudulent providers.
- Considering the extension of administrative remedies that are available to public insurers, as well as other federal legislative actions needed to address health insurance fraud and abuse.

For your reference, I have included a draft bill that we have prepared as a starting point for those who may be interested in drafting legislation authorizing a health care fraud commission.

Of further interest are the January 13, 1993, recommendations of a task force charged with examining the problem of health care fraud and abuse. The Secretary of Health and Human Services, the Director of the Office of Management and Budget, and the Attorney General, as task force members, developed specific recommendations that could serve as a good reference in drafting health care fraud and abuse legislation.

Please feel free to call me or Assistant Director Ed Stropko at 202-512-7119 to help answer any questions.

Sincerely yours,

Janet L. Shikles
 Janet L. Shikles, Director
 Health Financing and
 Policy Issues

Enclosure

A BILL

To create a national commission for studying fraud and abuse in the health insurance system, and making recommendations to the Congress on ways to combat such fraud and abuse.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "National Commission to Combat Health Insurance Fraud and Abuse Act of 1992".

SEC. 2. PURPOSE.

(a) PURPOSE OF ACT.--The purpose of this act is to establish a National Commission to Combat Health Insurance Fraud and Abuse (hereinafter referred to as "Commission").

(b) PURPOSE OF COMMISSION.--The purpose of the Commission is 1) to study fraud and abuse in the United States health insurance system, and 2) report recommendations to the Congress for combatting fraud and abuse in the health insurance system.

SEC. 3. ESTABLISHMENT.

There is hereby established an independent National Commission to Combat Health Insurance Fraud and Abuse.

SEC. 4. MEMBERSHIP.

(a) APPOINTMENT.--The Commission shall be composed of--

(1) the Inspector General of the Department of Health and Human Services (hereinafter "Inspector General"), who shall serve as Chairman; and

(2) 14 other members, who shall be appointed jointly by the Secretary of Health and Human Services, the Attorney General of the United States, and the Comptroller General of the United States, after consultation with the Chairman.

(b) QUALIFICATIONS.--To ensure that membership of the Commission shall be fairly balanced in terms of the points of view represented and the functions to be performed, members of the Commission (other than the Inspector General) shall be appointed based on knowledge, training, or experience involving the health insurance system, or legal issues affecting fraud and abuse investigations and litigation, from among--

- (1) individuals from the business community;
- (2) individuals from the health insurance industry;
- (3) individuals engaged in the practice of medicine;
- (4) individuals engaged in hospital administration;
- (5) State officials directly responsible for regulation of health insurance;
- (6) Federal officials responsible for the establishment, management, or oversight of health policy;
- (7) State or Federal officials involved in law enforcement related to health insurance fraud and abuse;
- (8) representatives of nonprofit organizations or foundations;
- (9) representatives from a Medicare Peer Review Organization; and
- (10) State Medicaid directors.

(c) VACANCIES.--A vacancy in the Commission shall not affect its powers, but shall be filled by the appointment of a qualified replacement by the Chairman.

(d) TERMS.--Members of the Commission shall be appointed to serve for the life of the Commission.

(e) COMPENSATION.--Members of the Commission shall serve without compensation, but shall be allowed travel expenses including per diem in lieu of subsistence, as authorized by section 5703 of title 5, United States Code, when performing Commission duties.

SEC. 5. POWERS OF THE COMMISSION.

(a) ACTIVITY OF COMMISSION.--The Commission may begin to carry out its duties when at least 11 members of the Commission are appointed.

(b) QUORUM.--A majority of the members of the Commission shall constitute a quorum for the transaction of business.

(c) Hearings.--The Commission may, for the purpose of carrying out this Act, conduct such hearings, sit and act at such times and places, take such testimony, and receive such evidence, as the Commission considers appropriate.

(d) VOTING.--Each member of the Commission shall be entitled to 1 vote, which shall be equal to the vote of every other member.

SEC. 6. FUNCTIONS OF THE COMMISSION.

(a) Study.--The Commission shall study the incidence and types of fraud and abuse in the health insurance system with special emphasis on resolving problems encountered in detecting, investigating, and litigating cases of fraud and abuse in the health insurance system.

(b) Report.--Based on the study required under subsection (a) of this section, the Commission shall submit a written report to Congress not later than September 30, 1994 making recommendations for combatting fraud and abuse in the health insurance system, which shall include (but not be limited to) recommendations on--

(1) How investigation and litigation efforts should be organized and financed;

(2) Creating a model State statute for establishing State insurance fraud units and State laws to strengthen insurers' ability to pursue and recover from fraudulent providers;

(3) Mechanisms for sharing information among insurers to assist in detection and investigation;

(4) Mechanisms for sharing information to assist in litigation;

(5) Criteria for physician referrals to facilities in which they (or family members) have a financial or management interest; and

(6) The extension to private health insurers of administrative remedies currently available to public insurers.

SEC. 7. ADMINISTRATIVE.

(a) Meetings.--Regular meetings of the Commission shall be called by its Chairman and held at least semiannually. Special meetings shall be called at the discretion of the Chairman or at the request of one-third of the members.

(b) STAFF.--The Commission shall appoint a staff director, who shall be paid at a rate not to exceed the maximum rate of basic pay under section 5376 of title 5, United States Code. The staff Director, in consultation with the Chairman, shall arrange the employment of such professional and clerical personnel as may be reasonable and necessary to enable the Commission to carry out its functions, without regard to the provisions of title 5, United States Code, governing appointments in the competitive service, and

without regard to the provisions of chapter 51 and subchapter III of chapter 53 of such title, or of any other provision of law, relating to the number, classification, and General Schedule rate, except that no employee, other than the staff director, may be compensated at a rate to exceed the maximum rate applicable to level 15 of the General Schedule.

(c) OTHER FEDERAL PERSONNEL.--Upon request of the Chairman of the Commission, the head of any Federal agency is authorized to detail, without reimbursement, any personnel of such agency to the Commission to assist the Commission in carrying out its duties under this title. Such detail shall be without interruption or loss of civil service status or privilege.

(d) Information.--The Commission may secure directly from any Federal agency such information, relevant to its functions, as may be necessary to enable the Commission to carry out this subsection. Upon request of the Chairman, the head of the agency shall, to the extent permitted by law, furnish such information to the Commission.

(e) MAILS.--The Commission may use the United States mails in the same manner and under the same conditions as Federal agencies.

(f) CONTRACTS.--The Commission may enter into contracts with private firms, institutions, and individuals for the purpose of conducting research or surveys necessary to enable the Commission to discharge its duties under this Act.

(g) ADVISORY COMMITTEE.--The Commission shall be considered an advisory committee under the Federal Advisory Committee Act.

SEC. 8. TERMINATION.

The Commission shall terminate 90 days after submitting the final report required by this Act.

SEC. 9. AUTHORIZATION OF APPROPRIATIONS.

There are authorized to be appropriated not to exceed \$_____ for fiscal year 1993 and \$_____ for fiscal year 1994. Any sums so appropriated shall remain available until expended.

Mr. SCHUMER. I would like to underscore Mr. Schiff's suggestion. Get together and make a list of suggestions for us and send them to us. We would be eager to see those and give them very careful consideration.

Mr. Edwards.

Mr. EDWARDS. Thank you, Mr. Chairman. I am honored to be on this subcommittee. Thank you for your kind remarks, Mr. Chairman. This subcommittee has done magnificent work over the many years.

Mr. SCHUMER. Thank you.

Mr. EDWARDS. The FBI steadily has more cases, is that correct?

Mr. POTTS. Yes, we certainly do.

Mr. EDWARDS. Where do you get the cases? From complaints?

Mr. POTTS. Yes, sir. They come from a variety of places. They compromise complaints from citizens, from the health care providers, from private insurance companies.

Mr. EDWARDS. And you use them as the basis of your responses?

Mr. POTTS. Yes, sir.

Mr. SCHUMER. What is your record of prosecution over the last year or so.

Mr. POTTS. For the last year or two I think we had 172 convictions last year. I believe that since we have added additional resources, Mr. Edwards, we have about 150 agents that we are now applying to health care fraud, and that is an increase of about 100 that we have taken from other places in order to apply to this problem, and they have had a tremendous impact in this past year. I think you will see more of an impact on the convictions next year.

They have had a tremendous impact on indictments this year. We went from 82 indictments in 1991 to 409 last year in this area.

Mr. EDWARDS. That is a very important part of the health care reform that we hope to be completing this year and next. But there is a lot more out there, is that correct?

Mr. POTTS. There is a lot more out there. We don't pretend we have more than touched the tip of the iceberg. As a matter of fact, the more cases we learn—the more we learn and educated we become about how these frauds are committed and how to investigate them and we just—it is overwhelming in terms of the amount still out there.

Mr. EDWARDS. What is the crime?

Mr. POTTS. What is the crime in terms of the various—

Mr. EDWARDS. Federal jurisdiction.

Mr. POTTS. We have an Anti-Kickback Act for Medicare and Medicaid. We have mail fraud, wire fraud. We have RICO and a lot of them—we are seeing more and more organization to the health care frauds.

Several years ago the FBI got involved in health care fraud. It was kind of a case-by-case type of investigation. Now we are seeing more and more situations where we can link cases together like the Goldpill investigation where we had across the United States investigations in that area. So we see more organization, and we will see more RICO investigations possibly.

Mr. EDWARDS. Thank you. Sounds like you are all doing a very good job. It is good to hear.

Thank you, Mr. Chairman.

Mr. SCHUMER. Thank you, Mr. Edwards.

Mr. Ramstad.

Mr. RAMSTAD. Thank you, Mr. Chairman.

My question concerns the use of administrative subpoenas in the white-collar investigations. I believe the inspectors general have authority to use the administrative subpoenas in white-collar crime investigations. My question to you, Mr. Potts, does the FBI have similar authority to use these subpoenas in getting financial and business records in these health care fraud investigations?

Mr. POTTS. Not in health care, no, sir. We only have those in the area of drug investigations and have not received that authority in the area of health care fraud or any other white-collar crime area.

Mr. RAMSTAD. Mr. Chairman—Mr. Potts, would that be a legislative recommendation that you would make?

Mr. POTTS. It would be something that the FBI has been very interested in, and I think it is something that we would probably put on the plate to discuss with the new Attorney General, but in the past we have not had a lot of success getting legislation put together to come up here.

Mr. RAMSTAD. Thank you, Mr. Potts. If I can be helpful or other members of the subcommittee in this regard, please let us know because this would be a valuable tool in your investigation.

Mr. POTTS. I believe it would, too. Thank you.

Mr. RAMSTAD. Thank you.

[The prepared statement of Mr. Ramstad follows:]

PREPARED STATEMENT OF HON. JIM RAMSTAD, A REPRESENTATIVE
IN CONGRESS FROM THE STATE OF MINNESOTA

Mr. Chairman, I want to commend you for holding this important oversight hearing. With 37 million people lacking health insurance, and health care spending at \$700 billion a year and rising fast, the people of this country are legitimately turning to Congress for answers.

As we pursue efforts to reduce the cost of health care and expand health care coverage to everyone, it's become obvious to me that if we want to succeed, we must combat health care fraud more effectively.

I was shocked to learn that the GAO estimates that 10% of our total health care expenditures are lost to fraud and abuse. Imagine how much we could improve health care in this country if we had an extra \$70 or \$80 billion to spend to make people better, rather than continue to line the pockets of health care thieves?!

I'm anxious to hear the testimony today in order to learn more about the true magnitude of the problem. Hopefully, we will hear some ideas on how to better combat health care fraud from the people who know this issue so well.

I'm glad to see that Joyce Hansen, Director of Claim Support Services for Northwestern National Life Insurance Company, which is headquartered in Minneapolis, will be testifying in the last panel. The numerous case studies of fraud she has recorded illustrate precisely how fraud can rob us of the health care value we deserve. I'm pleased to welcome Ms. Hansen to the hearing, as she is also a constituent.

Again, thank you, Mr. Chairman. I look forward to working with you on legislation to address this issue early this year.

Mr. EDWARDS. I have one more. The crimes you describe are pretty clearly State and local crimes, too. Are there quite a number of prosecutions going on in the various counties and cities of our country?

Mr. POTTS. I would guess that the majority of the prosecutions are Federal from my experience. I think there are probably a number of prosecutions by State but—

Mr. SCHIFF. If the gentleman will yield on that point.

Unless it has changed—it has been several years since I left the district attorney's office—the Federal Government helps fund the fraud units, and they are State entities, but they are heavily, federally subsidized because of the Federal involvement. But, I know there are State and local prosecutions.

Mr. SCHUMER. In New York we have such an office.

Mr. SCHIFF. I yield back to the gentleman.

Mr. EDWARDS. It ought to be recorded in the FBI's crime statistics reporting, isn't that correct?

Mr. SCHUMER. Good idea.

Mr. MOREY. Mr. Chairman, 38 States have Medicaid fraud control units under the jurisdiction of the OIG. We fund those folks. They have about a thousand employees, and they do a good job. I think their statistics last year were 700 Medicaid fraud convictions.

Mr. SCHUMER. Let me ask a couple of quick final questions. Do you find that sting operations are a very effective way to deal with this? Dr. Marr was a one-man sting operation. Is that a good way to get through this or are there better or quicker ways?

Mr. MOREY. There is one way that has been really effective, and that is through the qui tam statute where somebody has an incentive to come out and bring this crime into the forefront. I would say the National Health Laboratories was probably our largest settlement, probably the largest in the Federal Government, \$100 million. By the time we tacked on the State it was \$110 million. And that has a qui tam complainant in it.

Mr. POTTS. I think it is correct, if you are lucky to have somebody on the inside. Frequently, you are dealing with records that cannot always be depended on and are difficult in a complex case to present that to a jury in a court. Frequently, it is what goes—it is one-on-one type of dealing with the doctor or pharmacist and the patient. So in those kinds of cases it has been very productive for us to be able to have undercover operations.

Mr. SCHUMER. A final thing. You all mentioned how the billing records are so difficult and impervious. What has stood in the way of standardizing the billing records? It seems to me an obvious thing to do, not only for detection of fraud but also for administrative purposes. Now that we are going to electronic processing of claims, it makes absolute sense to do it. What is holding it back?

Ms. SHIKLES. I think you are going to have to pass legislation that will require it because there is going to be quite a bit of cost involved. Insurers have started meeting together and focusing on the issue, but they have developed their own systems and paperwork and own requirements so there will be an investment that will be required to move toward one form, one billing number, and I think it is going to take a legislative mandate from Congress.

Mr. SCHUMER. HCFA would not be interested in mandating it on their own?

Ms. SHIKLES. HCFA would be interested in doing it, but it wouldn't have authority. It would only have authority for providers in its own programs.

Mr. SCHUMER. Have they tried to do that for them?

Ms. SHIKLES. They are moving slowly just to do it for themselves.

Mr. SCHUMER. That is another thing to look at. We have so many areas that we must explore.

Mr. MOREY. Mr. Chairman, a final comment.

Oftentimes we will adjudicate this through the Federal system, and the Federal Government ends up being protected. But what we have left undone is the private sector. Like, for example, in that \$100 million settlement the Federal Government has insured that will not happen to us again, but we didn't fix anything for the private sector. There ought to be something here in—when we adjudicate something and we know it is wrong for the Federal sector, that we also correct the private sector. Example, my administrative sanctions, if they are so out of tune that Medicare or Medicaid will not pay their bills why should an insurance company or why should they be able to practice in the private sector?

Mr. SCHUMER. On the toll-free hot lines or hot lines with a rebate, one person, who I respect, said, out of a hundred people who call, 99 are not giving useful information. That one is often minor and trivial so it doesn't pay.

Do you agree with that?

Mr. POTTS. We have had some mixed results with 1-800 numbers. I think, however, they are very appropriate to give the public. They need a place to complain. They need a number that they know they can call and it is going to be recorded. And you may get a majority of the phone calls that don't result in major investigations or don't—you can't do anything for the person, but I think they are worth their money just because it gives one repository for someone to call in and register their complaint or their information.

Ms. SHIKLES. I think you are right. Our experience with the Medicare program is most of the calls are because the person can't understand the bills. A small number do turn out to be terribly fruitful, but I think it is important to just also let the providers know that someone is watching these bills.

And what is of particular concern as we move more toward electronic processing because it saves processing on the claims payment, nobody will watch the bills anymore.

Mr. SCHUMER. It is a large black hole. It is terrible.

Ms. SHIKLES. That is right. So at least the beneficiary will get a copy and be able to phone someone up. You are home free.

Mr. SCHUMER. What astounds me about this is it is almost as if there is a cancer inside of you from your ankles to your head and no one detected it. The amount of fraud is so huge, there are so many tentacles all over, and it is so hard to find them.

Ms. SHIKLES. Exactly right. You saw in the rolling labs case you are talking about small amounts of money you can bill fast electronically over and over and over.

Mr. SCHUMER. Over and over and over, right. We have to do something about that.

I want to thank this panel. I think it was excellent in helping direct us.

The sole member of our third panel is a distinguished member of the medical community, Dr. Jerald Schenken, member of the board of trustees of the American Medical Association, having served on the board since 1985. In addition to his other work with the AMA, Dr. Schenken has served on the White House Council on Aging and White House Conference on Small Business. He is a pathologist in private practice in Omaha, NE, and is involved in numerous civic activities in his community.

I want to thank you for being with us this morning, Dr. Schenken. Your prepared statement has been received and will be entered into the record without objection. If you would begin your testimony.

STATEMENT OF JERALD R. SCHENKEN, M.D., MEMBER, BOARD OF TRUSTEES, AMERICAN MEDICAL ASSOCIATION, ACCOMPANIED BY HILARY LEWIS, J.D., DIVISION OF FEDERAL LEGISLATION

Dr. SCHENKEN. Thank you, Mr. Chairman.

The vast majority of physicians and AMA members are conscientious, caring and honest. I am here to represent them. As for the rest, the unethical and fraudulent, I am here to offer you my help as well as that of the AMA to rid the profession and the Nation of this plague upon both our houses. The fact that many, if not most, of the fraudulent operations are not run by physicians at all further complicates our problem.

To effectively address health care fraud, the AMA believes that rigorous scrutiny should be brought to bear regarding the existing nature and scope of health care fraud. We believe that any legislative solution should contain a number of elements.

First, we support the establishment of an intergovernmental commission to further investigate the nature, magnitude and costs involved in health care fraud and abuse.

Second, we strongly urge that a clear definition of health care offense be incorporated into any legislative proposal. Health care fraud and abuse is currently prosecuted under the mail and wire fraud statute and the Medicare law. These two provisions must be reconciled in any approach that is ultimately formulated in order to: one, attain consistency; two, focus enforcement efforts and preclude harsh sanctions for inadvertent or legitimate mistakes such as billing errors; and, three, impose penalties commensurate with the offense committed.

The AMA urges that any definition of the health care offense include knowing, willful and fraudulent intent on the part of the health care professional or provider. As the FBI stated, we believe that billing errors and most utilization concerns don't constitute fraud. Such issues relate to the practice pattern of physicians and are addressed through practice guideline and peer review mechanisms. Thus, the parameters of a fraudulent practice must be clearly articulated.

Ours is a profession that relies on public and individual trust as a vital element in providing successful medical care. Clearly, any number of bad apples is too many.

The AMA is already pursuing a number of antifraud activities. For example, AMA officials have assisted the FBI in training agents to ferret out fraud. We have also offered our network of State and specialty societies, boards and entities with self-regulatory mechanisms in place to combat criminally fraudulent activities.

The AMA has established a system whereby medical societies or individual physicians can report fraud to the AMA by dialing our toll-free member service number.

Unfortunately, law enforcement alone will not create an environment in which fraud and wasteful activity will only be a marginal concern.

Mr. Chairman, it is clear that bills for medical services are not, often not, sent to patients who could identify fraud, at least for services which were billed but not provided. A golden opportunity is missed. It is not missed in Medicare, but it is often generally missed. Many businesses and insurers are currently asking patients to review such bills. The AMA supports full discussion of services by patients and physicians and supports such review.

Mr. Chairman, the AMA has filed a petition with the Federal Trade Commission seeking to remove the limitations that restrict the medical profession from pursuing additional efforts to discipline itself.

We also support H.R. 47 which would provide an exemption from the Federal antitrust laws for medical self-regulatory entities engaged in enforcement activities designed to promote quality health care. Such an exemption would enable the medical profession to play an active part in dealing with health care fraud and abuse.

Mr. Chairman, it is difficult to emphasize the importance of this effort. I am old enough to have practiced before there were such restrictions and know how effective medical societies could be in disciplining the profession.

Let me make one point clear, Mr. Chairman. If our initiatives are viewed by physicians as effective in rooting out fraudulent physicians when they are involved and true hustlers and charlatans while, at the same time, being fair to conscientious physicians who make unintentional billing errors, you will have our enthusiastic support. If, however, the bill, the enforcement mechanism or regulations appear to harass legitimate providers more and convict criminals less, professional support will wane. The AMA must and will work with you to make sure this does not happen.

The AMA appreciates the opportunity to appear before this subcommittee. At this time I would be pleased to respond to questions, and I would request, Mr. Chairman, that the oral statement be put in the record as well if that is possible.

Mr. SCHUMER. Without objection, and thank you, Dr. Schenken. [The prepared statement of Dr. Schenken follows:]

PREPARED STATEMENT OF JERALD R. SCHENKEN, M.D., MEMBER,
BOARD OF TRUSTEES, AMERICAN MEDICAL ASSOCIATION

Mr. Chairman and Members of the Subcommittee:

My name is Jerald R. Schenken, MD. I am a pathologist from Omaha, Nebraska and a member of the Board of Trustees of the American Medical Association (AMA). Accompanying me is Hilary Lewis, JD, of the Association's Division of Federal Legislation. On behalf of the AMA, I want to express our appreciation for the opportunity to appear before the Subcommittee to provide our views on the subject of health care fraud and abuse.

While the scope of this problem is clearly substantial, its precise dimensions remain difficult to quantify. One point, however, must be emphasized: whatever resources are expended for fraudulent and wasteful practices diverts the use of funds and efforts from meeting legitimate health care needs. The AMA urges that activities be undertaken to identify and eliminate abusive, wasteful and fraudulent practices.

COST OF HEALTH CARE FRAUD

In order to effectively address the issue of health care fraud, its proportions and magnitude must be accurately identified. A May 1992 study issued by the General Accounting Office (GAO) declares that "health industry officials estimate that fraud and abuse contribute some 10 percent to \$700 plus billion in U.S. health care spending." A more recent GAO study, issued in December 1992 on fraud and abuse in the processing of Medicare claims, states that Medicare's losses cannot be quantified precisely and observes that "health industry experts estimate that fraud and abuse could account for as much as ten percent of the nation's total health care costs."

The AMA believes that more rigorous scrutiny must be brought to bear regarding the existing nature and amount of health care fraud. Only careful examination of its scope will ultimately yield the most effective solutions to this difficult problem. Further information is needed.

In an effort to identify areas of fraudulent practice, the AMA would be pleased to work with the federal government in studying the extent to which health care fraud permeates the current environment. Our own survey data, for example, have elicited valuable information on the incidence of hospitals that require physicians to make payments for hospital services. In our study, physicians were asked: (1) whether any hospital had ever requested the physician (or the physician's practice) to make payments to the hospital for the privilege of serving patients there; and (2) whether the physician had ever been asked to make payments

to a hospital for the privilege of utilizing space, supplies, equipment, utilities, hospital employees, or billing information. (See Attachment A.) In our view, the proper development of similar data on other possible abuses that are present within our health care system will result in the development of the most effective solutions to this problem.

We strongly concur with the recommendation issued by the GAO in the May 1992 study that calls for the establishment of a national commission to develop comprehensive solutions to health insurance fraud and abuse. We also support the recommendation in the December 1992 GAO study advocating a nationally coordinated effort to combat fraud and abuse.

LEGISLATIVE APPROACHES

A number of bills were introduced in the 102nd Congress to address the problem of health care fraud and abuse, including H.R. 5449, the "Health Care Fraud Prosecution Act of 1992, sponsored by the Chair, Representative Charles Schumer, (D-NY) and Representative Rosa De Lauro (D-CT). Senator Joseph Biden (D-DE) introduced similar legislation, S. 2652, last Congress. We commend you, Mr. Chairman, and the Subcommittee, for examining this critical issue today. The AMA is concerned about this serious matter and was previously involved in working with the Senate Judiciary Committee in the 102nd Congress on these issues.

The AMA believes that any legislative solution that is formulated must contain a number of elements. We submitted a statement to the Senate Judiciary Committee on September 10, 1992 outlining many of these elements. The Senate passed S. 2652 late in the last session of the

102nd Congress that included some, but not all, of our suggestions. We strongly urge your subcommittee to consider our comments. First, we support the establishment of an intergovernmental commission to investigate the nature, magnitude and costs involved in health care fraud and abuse.

Second, we strongly urge that a clear definition of a "health care offense" be incorporated into any proposal that is considered. Health care fraud and abuse is currently prosecuted under sections 1341 and 1343, Title 18, United States Code, the mail and wire fraud statute, as well as under Title 42, Medicare. These two provisions must be reconciled in any approach that is formulated in order to: (1) attain consistency; (2) preclude harsh sanctions for inadvertent or legitimate mistakes, such as billing errors; and (3) impose penalties commensurate with the offense that is committed.

While a physician is, of course, responsible for actions performed in his or her name, the physician should be found to be acting with the intent to commit a fraudulent act where a court imposes a severe sanction. To address this, we urge that any definition of a "health care offense" include knowing, wilful or fraudulent intent on the part of a health care professional or provider. It will, therefore, be necessary to amend more than the mail and wire fraud statutes in order to achieve this purpose. If the Criminal Code, Title 18, is used as the primary vehicle for prosecution of health care fraud and abuse in furtherance of Medicare (Title 42) offenses, fines and imprisonment exceeding the gravity of the

offense will result. The AMA, therefore, advocates legislation prescribing penalties in accordance with Medicare's violations. We strongly discourage, moreover, any effort to impose a prosecutorial scheme on the health care industry bearing the indicia of a RICO-type statute with draconian penalties disproportionate to the offense committed. Fraudulent health care practices may be better ameliorated through the creation of legal means other than the blueprint now in place to fight organized crime.

As outlined below, the AMA also favors the award of grants to medical societies for the creation of programs to address fraud and abuse, such as those provisions embodied in H.R. 5449.

ETHICAL ISSUES

Where a physician provides care in a fraudulent manner, numerous ethical breaches occur, and the AMA has addressed these matters through various ethical pronouncements. These statements require ethical physicians to accept the responsibility to report colleagues who are engaged in fraud or deception. The AMA Principles of Medical Ethics state, as follows:

A physician shall deal honestly with patients and colleagues, and strive to expose those physicians deficient in character or competence, or who engage in fraud or deception.

Opinion 9.031 of the AMA's Council on Ethical and Judicial Affairs (CEJA) outlines the physician's obligation to report impaired, incompetent, and unethical colleagues in accordance with the legal requirements in each state pursuant to the guidelines outlined in the opinion. With respect to the reporting of unethical conduct, the opinion specifically states:

Unethical conduct that threatens patient care or welfare should be reported to the appropriate authority for a particular clinical service. Unethical behavior that violates state licensing provisions should be reported to the state licensing board. Unethical conduct that violates criminal statutes must be reported to the appropriate law enforcement authorities. All other unethical conduct should be reported to the local or state medical society.

Where the inappropriate behavior of a physician continues despite the initial report(s), the reporting physician should report to a higher or additional authority. The person or body receiving the initial report should notify the reporting physician when appropriate action has been taken. Physicians who receive reports of inappropriate behavior have an ethical duty to critically and objectively evaluate the reported information and to assure that identified deficiencies are either remedied or further reported to a higher or additional authority. Anonymous reports should receive appropriate review and confidential investigation.

AMA INITIATIVES AND RECOMMENDATIONS

The AMA recognizes that additional efforts must be undertaken to attack health care fraud and abuse, especially inasmuch as it transcends the medical profession, reaching into many segments of our society.

Unfortunately, people and entities from all walks of life have been found culpable in contributing to the magnitude of the problem.

The medical profession remains committed to rendering high quality medical care to its patients on an ongoing basis, and the AMA is proud of the work of our professional community. While some physicians have been implicated in health care fraud activities, we note that their numbers have been minimal. Even this level of physician participation is unacceptable, and the AMA does not condone fraudulent activity on the

part of even one individual. In a profession that relies on public and individual patient trust as a vital element in providing successful medical care, any number of "bad apples" is too many.

The AMA stands ready to assume an active role in identifying those who would profit by improper use of their authority to practice medicine. We pledge to work with the Congress and appropriate law enforcement agencies in a cooperative endeavor to attain the goal of eliminating health care fraud in all of its forms. To this end, the AMA is pursuing a number of activities.

I. Cooperation with Federal Bureau of Investigation (FBI)

In 1992, representatives of the AMA met with the Federal Bureau of Investigation to discuss issues relating to fraud and abuse. Throughout this very constructive session, FBI representatives made it clear that physicians are not responsible for the vast majority of health care fraud and abuse. The AMA, however, does not take comfort from the fact that the number of physicians who seek to gain through fraudulent practices is small.

We have agreed to provide assistance to the FBI in a cooperative endeavor as it attempts to identify and prosecute health care fraud. AMA officials have assisted the Bureau in training agents to ferret out fraud. We have also offered our network of state and specialty societies, boards and other entities to combat criminally fraudulent activities. The self-regulatory mechanisms of these organizations should be useful in detecting illegal activity.

2. AMA Fraud and Abuse Hotline

The AMA has committed resources to establishing a system whereby medical societies or individual physicians can report fraud through the AMA by dialing our toll-free member services number. After receiving such a call, the AMA will contact sources at the FBI to report the matter. We have notified state and county medical societies of this activity and requested that it be publicized to their membership. The Association has also stressed that physicians should report any invitation to engage in fraudulent activity.

3. Health Care Commission on Fraud and Abuse

While more criminal investigations by the FBI, the Inspector General and the states will succeed in eliminating some of the immediate problem, law enforcement alone will not create an environment in which fraudulent and wasteful activity will become only a marginal concern. Even a cursory examination of the "war on drugs" illustrates this point. As stated earlier, the most effective initial step will include accurate identification of the dimensions of health care fraud and abuse so that investigatory resources may then be focused in a manner that will address the causal agents and not merely the isolated criminals.

The establishment of a national commission on fraud and abuse would be beneficial, as it could explore mechanisms to facilitate fraud detection, such as allowing health benefit plans to exchange information for coordinating prosecution efforts and to ensure the availability of appropriate and effectively applied resources to law enforcement

authorities to combat fraud and abuse. However, any measures taken must proceed cautiously, as even seemingly innocuous actions, such as information exchange systems and other investigatory activities, must be carefully weighed against potential sacrifices of patient confidentiality protection. Through careful consideration of such concerns, the commission could provide a valuable means to target and focus activity to address this critical issue.

4. Professional Self-Regulation

The medical community is currently constrained from efforts to discipline itself by state and federal antitrust laws that inhibit the ability of organized medicine to assume an expanded professional self-regulatory and enforcement role. When medical societies have tried to exert their influence on economic matters, even where the issues involve fraud and abuse, antitrust provisions have precluded action. The AMA has recently filed a petition with the Federal Trade Commission (See Attachment B.) seeking to remove limitations that restrict the medical profession from pursuing additional efforts to discipline itself. To this end, the AMA also supports H.R. 47.

We believe that an exemption from the federal antitrust laws for medical self-regulatory entities engaged in enforcement activities designed to promote the quality of health care, which would be created under H.R. 47, would advance progress in this area. It would also enable the medical profession to play a more active role in the elimination of health care fraud and abuse. In addition, statutory immunity should be afforded to those who provide information in good faith leading to prosecution and

conviction of health care offenses. Any proposed legislative solution needs to incorporate this approach, and it must be carefully crafted to clearly illuminate the parameters of a fraudulent practice.

5. Medical Society Grants

Another mechanism for health care fraud and abuse detection should include the award of grants to medical societies for the establishment of programs specifically targeted toward this issue. Medical societies presently lack the resources to launch comprehensive initiatives to investigate and study these issues. The majority of their disciplinary activities are directed at problems relative to fee disputes, impaired physicians or sexual misconduct. An award grant program would better enable medical societies to explore mechanisms to facilitate fraud detection at the local level, work with state medical disciplinary agencies to identify those who commit health care fraud, and ensure that appropriate sanctions are imposed.

6. State Licensing Boards

The state medical and licensing boards, through their authority to license and discipline health care professionals, also have an important role to play in any organized effort to address health care fraud and abuse. The AMA urges the Subcommittee to pursue discussions with the Federation of State Medical Boards regarding possible strategies to achieve the goal of strengthening the ability of state agencies in this regard.

CONCLUSION

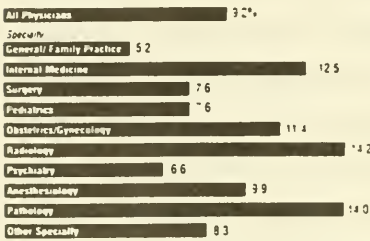
In conclusion, the AMA underscores its commitment to eliminate health care fraud and abuse wherever it exists. We welcome the opportunity to work with Congress and others on this issue so that our health care resources may be maximized to focus on our mutual goal -- the provision of quality health care to all of our citizens.

The AMA appreciates the opportunity to appear before this Subcommittee. At this time, we will be pleased to respond to questions.



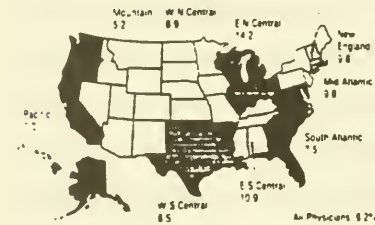
Physician Marketplace

Figure 1
Percentage of Physicians with Hospital Leases, by
Specialty, 1991*



* Source: AMA Socioeconomic Monitoring System, 1991 core survey of
ambulatory patient care physicians, excluding residents.

Figure 2
Percentage of Physicians with Hospital Leases, by
Census Division, 1991



* Source: AMA Socioeconomic Monitoring System, 1991 core survey of
ambulatory patient care physicians, excluding residents.

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Physician-to-Hospital Payments

Anecdotal evidence has suggested a rising incidence of hospitals requiring physicians to make payments for hospital services. Applying the reasoning of the Ninth Circuit Court of Appeals in *United States v. Lipkis*, 770 F.2d 1447 (1985), an October 1991 report from the Office of Inspector General concluded that an *illegal kickback* occurs when a contract between a hospital and a hospital-based physician calls for the rental of space or equipment or provision of professional services on terms other than fair market value. Data from the Socioeconomic Monitoring System (SMS) 1991 core survey permit an analysis of the potential magnitude of this problem. The data have been analyzed by David W. Eminson, Ph.D., of the American Medical Association's Center for Health Policy Research, and his findings are presented in the remainder of this report.

An upper bound on the number of physicians with potentially questionable contracts is provided by the proportion of physicians with a lease arrangement, whereby they, or their practice, compensates a hospital for use of services such as space, equipment and personnel (hereafter, referred to simply as a lease). Figure 1 shows that 9.2% of all physicians have such a contract. Significant variation occurs by specialty: the proportion of physicians with a lease ranges from a low of 3.2% among general/family practitioners to a high of 14.0% and 14.2% among pathologists and radiologists, respectively.

Regional variations in lease-contracting reflect both the geographic distribution of specialties and regional differences in contracting practices. As shown in Figure 2, physicians in the East North Central states most frequently reported having a lease, 14.2%, in contrast to physicians in the Mountain states, only 5.2% of whom reported having one.

Alternative measures of the extent of the problem identified by the Inspector General are provided by responses to two additional questions on the SMS survey:

Table 1
Percentage of Physicians Asked for Payments, 1991

	Either	Patient Privileges Only	Services Only
All Physicians	6.9%	3.4%	4.6%
<i>Specialty</i>			
General/Family Practice	3.1	1.9	1.3
Internal Medicine	6.4	3.2	3.9
Surgery	5.9	2.9	4.4
Pediatrics	9.3	6.1	4.2
Obstetrics/Gynecology	4.1	1.5	2.7
Radiology	11.4	4.6	10.8
Psychiatry	7.0	3.6	4.1
Anesthesiology	9.8	5.1	7.7
Pathology	12.2	3.6	11.1
Other Specialty	10.7	5.1	7.3
<i>Region</i>			
New England	7.9	3.7	5.0
Middle Atlantic	10.6	4.8	8.5
East North Central	7.8	3.5	5.4
West North Central	3.8	0.7	3.5
South Atlantic	4.7	2.6	2.8
East South Central	3.3	1.0	2.3
West South Central	5.4	2.2	3.9
Mountain	7.9	3.8	4.6
Pacific	7.1	5.1	3.5

Source: AMA Socioeconomic Monitoring System 1991 core survey of nonfederal patient care physicians, excluding residents.

(1) Whether any hospital had ever requested the physician (or the physician's practice) to make payments to the hospital for the privilege of serving patients there.

(2) Whether the physician had ever been asked to make payments to a hospital for the privilege of utilizing space, supplies, equipment, utilities, hospital employees, or billing information.

Table 1 summarizes the responses to these two questions. The first column of Table 1 shows the proportion of physicians who responded in the affirmative to either of the two questions. The proportions of affirmative responses to each question individually are reported in columns 2 and 3. Overall, 6.9% of physicians had been asked by a hospital for payments. This percentage appears to be at odds with the proportion of physicians who reported they had a lease with a hospital (9.2%). Because questions 1 and 2 encompass a wide range of hospital/physician financial arrangements and merely being asked to make a payment does not mean that the physician complied, it would be expected that this proportion would be higher than the proportion of physicians indicating that they had a lease. One plausible explanation for the apparent discrepancy is that the lead-in phrase "Has any hospital ever requested..." led physicians to report only instances where a hospital had initiated such a discussion.

Table 1 also provides breakouts by specialty and census region. The patterns largely parallel those observed on the earlier question. By specialty, pathologists and radiologists were most likely to indicate having been asked by a hospital to make payments. By region, physicians in the Middle Atlantic states were most likely to have been asked.

In order to assess the magnitude of the amounts involved, physicians who had been asked for payments were asked if they were currently making such payments and how much, per physician, those payments were. Slightly more than one-half indicated that they currently made such payments. The latter group reported average payments, per physician, of \$2325.

The data reported here should be interpreted with caution. The Inspector General concluded that an illegal kickback occurs when a hospital contract calls for payments *on terms other than fair market value*. These data do not reflect the presence or absence of the latter property in the payments that physicians are making to hospitals. Nonetheless, the data do delineate some boundaries as to the prevalence of kickbacks being sought by hospitals.

American Medical Association

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Donald S. Clark
Secretary
Federal Trade Commission
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Washington, D.C. 20530

Dear Mr. Clark:

Pursuant to 16 C.F.R. 1.1, the American Medical Association (AMA) and the Chicago Medical Society (CMS) hereby request an advisory opinion that would permit the AMA, its constituent medical societies, and its component medical societies to engage in professional peer review of physician fees pursuant to procedures developed by the AMA.¹

Under the AMA's contemplated program, state or county societies would perform most of the professional peer review of fees.² State societies would also act as appellate bodies for opinions or decisions of the county medical societies, and under some circumstances would act as the initial forum for

¹ Pursuant to the AMA's Constitution, constituent medical societies are "medical associations of states, commonwealths, territories or insular possessions which are, or which may hereafter be, federated to form the American Medical Association." Component societies "are those county or district medical societies contained within the territory of and chartered by the respective state associations."

² The AMA believes that many of these medical societies will adopt the proposed fee peer review procedures if they are found to be compatible with the antitrust laws by the Federal Trade Commission. See the letters of support from state and county societies submitted with this request. Indeed, CMS, which is the largest county medical society in the nation, has chosen to join the AMA in this request because it desires to conduct the review of complaints about physician fees in the manner requested for the procompetitive reasons that are discussed infra.

peer review of fees. The AMA would participate as the appellate body for opinions and decisions of the state societies, and under rare circumstances would initiate its own peer review proceedings.

The Federal Trade Commission (FTC) has issued advisory opinions about the operation of professional peer review of fees.³ The FTC has recognized that, properly managed, professional fee peer review can yield important procompetitive benefits.⁴ In particular, fee peer review can increase the flow of information about physician fees to patients, enabling them to compare fees when selecting a physician.

However, the FTC has also expressed concern that improperly managed fee peer review could result in price-fixing agreements and the⁵ advisory opinions and guidelines issued by the FTC have been so restrictive that few medical societies engage in fee review today. We believe they are unnecessarily restrictive and are thereby depriving patients of an important public service.⁶ In particular, we object to the FTC guidelines which advise that:

1. Opinions of the peer reviewers must be advisory only and not coercive—that physicians must not be required either to participate in the review process or to comply with the opinion of the reviewers; and
2. That physicians must not be subject to discipline for charging any particular fee or for refusing to adhere to the opinion of reviewers.

A complete summary of the AMA's proposed procedures for professional fee peer review is included in subsequent portions of this letter. In brief, the procedures would generally adhere to the FTC guidelines, but we make the two important changes described above. The process would involve mediation of

³ See, e.g., *Medical Society of Passaic County* (January 3, 1986); *American Podiatry Association* (March 13, 1984); and *Iowa Dental Association*, 99 F.T.C. 648 (1982).

⁴ *Ibid.*, and see "Peer Review and the Antitrust Laws," Remarks of Mark J. Horoschak, Assistant Director for Health Care, Bureau of Competition, Federal Trade Commission, before the AMA National Leadership Conference, February 25, 1990, and for the perspective of the Antitrust Division of the U.S. Department of Justice see: "Business Self Regulation, An Enforcement Policy of Cautious Tolerance," Remarks of Charles F. Rule, Assistant Attorney General, Antitrust Division, U.S. Department of Justice, Before the Chicago Bar Association, January 27, 1989.

⁵ See fn. 3, *supra*.

⁶ Horoschak, fn. 4, *supra*.

complaints about fees, but physician participation would be mandatory under the AMA procedures and physicians can be disciplined for fee gouging.⁷ While the emphasis of the AMA's proposed program is on mediation, the AMA and the CMS believe that medical societies should be able to discipline members who engage in egregious conduct.

The AMA and CMS believe that these differences would enhance the procompetitive benefits of professional fee peer review by medical societies. Almost all fee peer review carried on by component societies is in response to patient complaints. Mandatory participation would increase the flow of information to patients about fees, and it would increase patient confidence in the market for physician services. The ability to discipline fee gougers would also increase patient confidence in the market.

When a medical society cannot require a member to participate in fee peer review in response to a complaint, the patient is always unhappy, sometimes harmed and the profession is denied the ability to enforce its code of ethics in a critical respect.

The AMA has had intermittent discussions with prior Chairmen of the FTC for the relief sought here for over seven years. We have sensed greater flexibility and a broader perspective from this Commission on certain matters and we submitted a draft of this request for an advisory opinion to the staff of the Bureau of Competition for an informal reaction. Staff has responded by requesting a substantial amount of information in addition to the material set forth in this request. Some of the questions asked by staff are clarifications that have been addressed by modifying this letter. Other information requested can only be obtained by calling upon the experiences of the constituent and component societies. The AMA and the CMS are in the process of gathering that information and will submit it shortly, but we do not believe it is necessary given the nature of the modifications we are seeking. For the reasons stated here and in the cover letter to Chairman Steiger, it is past time to grant the relief we seek.

The Procedures Proposed By The AMA For Professional Peer Review Of Physician Fees

a. Intent of the AMA's Proposed Procedures

This request for an advisory opinion is being submitted as part of a broad, procompetitive effort to enhance professional self regulation by physicians. The goal is to respond to widespread disenchantment with the health care

⁷ Fee gouging has been long been considered unethical by the profession. See Opinion 6.05, "Fees for Medical Services", in the Code of Medical Ethics and Current Opinions of the Council on Ethical and Judicial Affairs of the American Medical Association (1992)

system by addressing the complaints of patients, payers, and others about individual physicians in light of the ethical code of the profession. It is essential that physicians address this lack of confidence if the market for physician services is to function effectively. The object of enhanced self regulation is to restore confidence by providing a means to resolve patient and payer complaints about individual physicians and by promoting adherence to high standards of conduct by physicians.

This effort to enhance professional self regulation is procompetitive because it should result in greater protection of patient interests and provide a greater flow of information about physicians to patients, payers, and others. Patients will have greater confidence that their interests will be observed and that they will not be exploited when being cared for by a physician. In addition, there will be more information available for patients to compare the characteristics of physicians when choosing a provider. Further, individual physicians will obtain more information about the patient perspective and are likely to respond by changing their practice procedures to improve the experience of the patient.

The AMA hopes to achieve enhanced self regulation by reviving a professional peer review structure that was once active, but which has become increasingly inactive in certain matters in recent years. The AMA and its constituent and component societies have in place the organizational structure necessary to handle complaints about fees and other matters from patients, payers, and others. In fact, most of these medical societies have bylaws that provide for standing committees designed to mediate and resolve patient grievances and to discipline members that engage in unethical conduct. Some of these societies hear patient complaints about fees. However, these committees have become inactive or underused in many, if not most, geographic areas. There are some county and state societies with active grievance committees, but most do not review complaints about fees. The disciplinary function has virtually stopped in most areas.

The AMA has proposed the fee peer review procedures at issue in this request for two reasons. First, The AMA and the constituent and component medical societies view fee peer review as an important activity. Second, because of its importance, an FTC approved set of procedures that enhances the ability of these committees to mediate complaints about fees and to discipline fee gougers would provide an excellent means to promote the use of the peer review system. As is discussed in the next section of this letter, one of the reasons why the peer review structure has become increasingly inactive is fear of litigation, especially antitrust litigation. An advisory opinion from the FTC which found that the proposed guidelines for fee peer review are compatible with the antitrust laws would provide assurances to medical societies that peer review can take place without excessive liability risks.

Medical societies consider professional fee peer review to be important because most medical societies regularly receive complaints from patients and

other persons alleging that a physician charged an unreasonably high fee. The complaints are made with the expectation that the medical society will be able to provide relief. In addition, on some occasions legislators and others have criticized medical societies for not doing more about physicians who overcharge. On a broader level, much concern has been expressed about rising health care costs and society's ability to pay for them. Medical societies want the ability to respond to these complaints and issues.

Another reason why fee peer review is considered to be important is that other issues often underlie and give rise to complaints about fees. Often these problems do not involve egregious or unethical conduct, but they are important for physicians to learn about and address. They include poor communications about the nature of the services provided by the physician, insensitive treatment by the physician or the physician's office staff, and patient dissatisfaction with the outcome of services. Physician fees often become the lightning rod for dissatisfaction with physician services. Mediation of fee disputes is an excellent way for these complaints to surface and be resolved. Medical societies believe that it is important for physicians to respond to these complaints in order to restore patient confidence in the market for physician services. It may be even more important to resolve these issues than to mediate fee disputes.

Another type of issue that often underlies complaints about fees is lack of agreement between physicians and patients about how services will be billed. For example, one type of complaint is colloquially known as "unbundling." That involves charging separate fees for services that a patient or payer believes should be combined into one service with one fee. Usually it is alleged that the fees charged for the unbundled services add up to a charge that is greater than the appropriate fee for the bundled services. The issue of service definition has become important in disputes about physician fees. Again, mediation is an ideal way to address this issue.

There are situations where egregious misconduct underlies a complaint about fees. For example, fee gouging is often accompanied by other unethical activity, such as fraud, taking advantage of a poorly informed patient, undue influence over a vulnerable patient, or the intentional provision of unnecessary services. There is a broad perception that physicians who engage in egregious misconduct are not punished, and are instead allowed to repeat their misdeeds. Medical societies believe that it is important that physicians who engage in egregious misconduct be held accountable if patient confidence in the medical profession is to be restored.

Finally, the AMA believes that enhancing professional fee peer review and physician self regulation in general will serve an important societal need. Patients want to have their complaints addressed, and the medical profession believes that it has the tradition and structure necessary to do the job effectively. Historically, the profession itself, as opposed to other

institutions or regulators, has done the best job at taking the actions necessary to build public confidence in the market for physician services.⁸

b. The Existing Committee Structure

1. Patient Grievance Committees and Physician Disciplinary Committees

As of 1987, almost all of the county medical societies had "patient grievance committees" (PGCs) and physician disciplinary committees (PDCs).⁹ The purpose of a PGC is to take complaints from patients about physicians and to resolve them, primarily through mediation. If a complaint involves a serious charge of misconduct, the PGC may refer it to a PDC or to a state or federal regulatory agency. PDCs hear serious charges of ethical violations by a physician that might result in an action that affects the physician's membership.

⁸ Throughout its history, the profession has responded to the need to solve health care problems and to regulate itself in the public interest. During the mid and late 19th century, the profession organized medical societies and developed a code of ethics to distinguish physicians from the many competing health care practitioners that did not adhere to safe and scientific methods. Subsequently the profession initiated and helped operate the system of state licensure of allopathic physicians. At the turn of the century, the profession reformed the medical education industry and succeeded in eliminating the practice of granting diplomas for a fee and in closing substandard medical schools. A system of accrediting medical schools was developed that continues today, and which is operated by organized medicine. During the early part of the twentieth century, systems for accrediting graduate medical education programs and hospitals were developed by the profession, and the board certification of the American Board of Medical Specialties was organized. The net result has been the training of hundreds of thousands of physicians of high levels of competency and integrity, and their efforts to deliver high quality medicine has been an extraordinary success story. The impetus and basic organizational structure for the system has come from the profession itself, in particular, the American Medical Association. See generally, Morris Fishbein, M.D., A History of the American Medical Association, 1847-1947, W.D. Saunders Company, Philadelphia, Pa. (1947); Frank D. Campion, The AMA and U.S. Health Policy Since 1940, American Medical Association, Chicago, Illinois (1984); and Paul Starr, The Social Transformation of American Medicine, Basic Books, New York (1982).

⁹ Directory of Activities, Volume II, 1987, State and County Medical Associations, American Medical Association, Chicago, Illinois (1987).

State medical societies also operate PGCs and PDCs. However, county medical societies are intended to handle initial complaints, with state medical societies acting as an appellate body for parties dissatisfied with the opinions or decisions of the county societies. State PGCs and PDCs will handle initial complaints for counties in rural areas that do not have sufficient members or staff to operate committees. In addition, state PGCs and PDCs usually have discretion to handle initial complaints from any area in appropriate situations.

The AMA does not have a PGC or a PDC. However, the Council on Ethical and Judicial Affairs of the AMA (CEJA) acts as an appellate body for parties dissatisfied with opinions or decisions of state PGCs and PDCs. CEJA also is authorized to conduct its own investigation and hearings into charges of unethical conduct in appropriate situations.

The most active PGCs are operated by county societies that cover large metropolitan areas. These counties have a substantial membership, sometimes larger than rural states, and have the resources to operate active PGCs. The AMA believes that many counties do not have active PGCs, and states are not very active in this area either.

Counties and states have not been active in operating PDCs. The AMA does not have precise information about the operations of PDCs, but it appears that PDC activity has almost halted except in a few large states or counties.

There are several likely reasons for the low level of activity in PDCs. One is fear of litigation. As of 1987, ten state societies and 13 county societies reported that they had been investigated by the FTC, the United States Department of Justice (DOJ), or another government agency during the previous five years. Ten state societies and 20 county societies were sued by a member or a nonmember physician during the same period.¹⁰ Many of the investigations and lawsuits concerned antitrust issues associated with membership. Defense of a lawsuit is a major expense to a state or county society. Many have decided to minimize their exposure to lawsuits by reducing PGC activity and PDC activity.

In addition to fear of litigation, other factors that may cause a low level of activity are a shortage of resources, and a natural disinclination to engage in disciplinary functions that might adversely affect a peer. These factors, combined with fear of becoming embroiled in expensive litigation, have been powerful disincentives.

Currently, the AMA is encouraging county and state medical societies to activate their PGCs and PDCs. As part of this effort, the AMA is preparing to

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Direction of Activities: Fin 10, supra

handle more appeals from state PDCs and PGCs, and it is also providing guidance to state and county societies about how to operate the committees.

2. Chicago Medical Society's Existing Committees

Pursuant to its bylaws, the CMS has standing Ethical Relations and Physicians Review Committees and Subcommittees on Fee Mediation and on Medical Practice. Under the CMS bylaws, failure to cooperate with these committees and subcommittees is grounds for discipline. However, as a matter of custom and practice, CMS has excepted fee peer review from mandatory participation. Members have not been required to cooperate with fee peer review and have not been disciplined if they refuse to participate.

The CMS Ethical Relations Committee is comparable to a PDC and is responsible for disciplinary actions against members, which could include censure, probation, suspension or expulsion.

The CMS Physicians Review Committee is comparable to a PGC. Its Subcommittee on Medical Practice is responsible for complaints concerning the quality and utilization of medical care and has as its goal to open up communications, through mediation, to reach a mutually satisfactory resolution. The Subcommittee's opinion is advisory and nonbinding. An opinion adverse to the physician may be appealed to the Physicians Review Committee and, in turn, to the Illinois State Medical Society.

The Subcommittee on Fee Mediation is responsible for complaints concerning physician fees and has as its goal to open up communications, through mediation, to encourage a mutually satisfactory resolution. The Subcommittee's opinion is advisory and nonbinding. If it is the opinion of the Subcommittee that the fee is above the range of usual and customary fees charged in the geographical area for similar medical services, the physician may appeal to the Physicians Review Committee. Decisions rendered by the Physicians Review Committee in a fee mediation case cannot be appealed.

The efforts of CMS' Subcommittee on Fee Mediation have been frustrated by the Subcommittee's inability to discipline physicians engaged in egregious conduct, such as repeated instances of fee gouging.

c. Guidelines for the Operation of PGC's & PDCs

As stated earlier, the ANA has developed guidelines for the operation of PDCs and PGCs. These guidelines include procedures for ensuring basic fairness to the parties involved, such as minimizing conflicts of interest among reviewing physicians and other "due process" style safeguards. In addition, the guidelines have other features designed to provide for the appropriate disposition of various types of complaints. Many of the guidelines are drawn from the historical practices of the PGCs and PDCs, and some of the guidelines

are new. As a whole, the guidelines are a blend of existing practices and new recommendations.

These guidelines apply to all types of complaints handled by PDCs and PGCs, including the handling of complaints about fees. The guidelines also include a section about the handling of fee complaints in particular. The general guidelines are summarized below, and a summary of the guidelines for fee complaints follows immediately after.

1. General Guidelines

The AMA recommends that PGCs and PDCs screen complaints immediately after receipt to determine whether they should be handled by the committee, or referred to another committee or entity, or both. For example, state PGCs should generally refer complaints to the county PGC where the physician involved resides. PDCs should refer complaints that do not involve serious charges of misconduct to PGCs, and PGCs should refer complaints to a PDC when there is reason to believe that serious misconduct is involved.

If there is reason to believe that a threat to the health of the physician's patients exists, then the state's licensing board and the physician's hospital should be notified immediately. When there is reason to believe that a violation of law has occurred, then the appropriate government law enforcement agencies should be notified. A PGC or PDC might hold parallel proceedings when a state licensing board or licensing agency is notified, or it might wait for the outcome of any government actions, depending on the circumstances.

After screening of a complaint by a PGC, it should be investigated by one or more members of the PGC. An investigation should include interviews of the complaining party and the physician complained of¹¹, interviews of other physicians in the physician's field of practice, review of relevant documents, and other materials. Upon completion of the review, the reviewer should make a report to the full PGC, which should then make one of the following findings: (a) the physician did not act improperly, (b) the matter should be referred to the PDC and/or another entity for further proceedings, (c) the physician acted inappropriately but not enough to warrant disciplinary proceedings or proceedings by an outside agency, or (d) efforts should be made to resolve the matter through mediation. In situations where a physician has acted inappropriately, but not enough to warrant further proceedings, the PGC may require the physician to receive some education and agree to desist from the inappropriate conduct.

During mediation, the PGC should encourage the physician and the complainant to fully discuss their relative positions, with a view towards arriving at a

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At the present time, physician cooperation with investigations of fee complaints is voluntary

settlement. Mediation should include education of both the complainant and the physician regarding the appropriate expectations and conduct of each. While settlements are voluntary, the medical society may also require the physician to pursue certain educational activities as a condition of the settlement. The educational activities are designed to prevent repetition of the conduct which led to the complaint.

PGC decisions may be appealed. Some societies allow internal appeals from the PGC decision, others do not. Once proceedings are final at the society which heard the complaint, the decision may be appealed to the next level of society. Counties appeal to states, and the state PGC decisions or appellate decisions can be appealed to the AMA. During appeals, complaints are not reinvestigated. The PGCs findings of fact are accepted if reasonable in view of the record.

PDCs should be independent of PGCs — there should not be overlapping membership between the two committees in a society. The procedures followed by PDCs are also more formal. They are designed to qualify for the safe harbors provided by the Health Care Quality Improvement Act of 1986, 42 U.S.C. 11111 et seq., which immunizes the participants in good faith peer review from civil liability if procedures designed to ensure fairness to the physician under review are followed. The procedures are also tailored in any given state to meet additional requirements imposed by state law for the conduct of peer review. Specific steps are spelled out for providing notice of the grounds for potential disciplinary action, notice of the disciplinary proceedings, the conduct of the hearings, providing notice of the decisions, and appeals.

A physician found by a PDC to have engaged in unethical conduct may be subject to a range of sanctions¹². They include:

- (a) Requiring the physician to undertake a specific program of remedial education.
- (b) Requiring the physician to participate in a program of public service.
- (c) Reprimand, censure, suspension of membership or expulsion from membership.
- (d) Monitoring of the physician's practice for a specified period of time to ensure that corrective action has been taken.
- (e) A fine to be paid to the medical society, or, if appropriate, restitution to the patient.

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At the present time, sanctions do not apply to fee gouging

- (f) Report to the state medical board with a recommendation that action or investigation be initiated.
- (g) A combination of the sanctions listed in (a)-(e).

Factors in determining a sanction include not only the severity of the misconduct, but whether it was a first offense or part of a pattern of misconduct. More serious sanctions can also follow if, for example, a physician fails to participate in a program of remedial education or public service.

As is the case with PDCs, appeals may or may not be available within the society. Once the decision is final, it may be appealed to the next level, normally a state society, and then to the AMA.

Adverse actions taken by a PDC may be subject to federal and state reporting requirements. Under the federal Health Care Quality Improvement Act, any "professional review action" which adversely affects the membership of a physician must be reported to the state licensing board, which in turn reports to the National Practitioner Data Bank. Under the Act, "professional review actions" are those based on the competence or professional conduct of a physician, where the professional conduct affects or would adversely affect the health or welfare of a patient¹³. An action adversely affects membership, by reducing, restricting, suspending, revoking, denying, or failing to renew membership.¹⁴

Many states require by law that determinations of unprofessional conduct related directly to patient care be reported to the licensing board. In addition, a PDC may make other disclosures. If there is a finding that substandard care has been provided, the peer review committee of the physician's hospital should be notified. Normally, reports of adverse actions by PDCs should be disclosed to the society's membership and the public through vehicles such as state medical society journals. However, in some cases it may make sense to impose a sanction privately, as where the offense is not

¹³ *It is uncertain whether fee-gauging would fall within the definition of a professional review action. Economic injuries such as being overcharged do not seem likely to affect the "health" of patients, but they might be considered to affect the "welfare" of patients.*

¹⁴ *A physician who is being considered for disciplinary action may seek to avoid the procedure by resigning. Under the Health Care Quality Improvement Act, resignations which take place during the pendency of a hospital peer review procedure must be reported. However, it is not clear whether resignations during the pendency of a medical society peer review process must be reported.*

egregious and the physician is a first time offender, or where there is a referral to an impaired physician program.

Ordinarily, PGCs and PDCs will have jurisdiction over medical society members only. Participation and cooperation with PGC and PDC activities is mandatory, and failure to cooperate is grounds for discipline. However, the AMA recommends that county and state societies encourage nonmembers to participate in PGC or PDC proceedings when complaints are received about them. In practice, some societies will accept a complaint about a nonmember only if the physician agrees to abide by the PGC or PDC procedures and decision. In the absence of an agreement, these societies will refer the complaint to the state licensing board or to another appropriate institution. Other societies will process a complaint against a nonmember without the nonmember's consent. The AMA believes that serious complaints about non-members who refuse to participate in a professional society's fee review process should be referred to the state licensing board.

Complaints may be filed by any person. Most commonly complaints are filed by patients, but they may also be filed by family or friends of patients, colleagues of the physician, or by third party payers.

d. How Fee Complaints Would Be Handled By PGCs and PDCs

Complaints about fees would be handled according to a specific set of procedures newly developed by the AMA. All fee complaints would first be referred to a county PGC covering the area where the physician resides, or the applicable state PGC if there is no county PGC. All complaints would be screened by the PGC to determine whether they should be referred to a state licensing board or a government enforcement agency. No complaints would be referred to a PDC without first being investigated by a PGC.

After investigation, a PGC would determine whether a fee complaint was a "level I" complaint or a "level II" complaint. A level I complaint would be a complaint that did not involve egregious conduct by the physician involved, and a level II complaint would be one which involves an allegation of egregious conduct that has a credible foundation. Egregious conduct would include situations where the fee charged arose from fraud, the exercise of undue influence over a vulnerable patient, taking advantage of the lack of knowledge of a patient, failing to inform a patient that an unusually high fee would be charged, intentionally providing unnecessary services, or other misconduct. It would also include charging a fee so high, for example two or three times the market level for a major procedure, as to constitute fee gouging¹⁵. Fees much higher than normal would not constitute fee gouging if

¹⁵ FTC staff has asked for clarification about what constitutes fee gouging, and, in particular, what standards would be used to evaluate whether fee gouging occurred. The current reference point for what constitutes gouging is provided by Opinion 1 of the Code of Medical Ethics and Current Opinions of the Council on Ethical and

(Footnote continued on next page)

agreed to by a fully informed and competent patient or payer that was not subjected to undue influence. Complaints about fee gouging made by colleagues of the treating physician or by persons other than the patient would be reviewed to determine if the fees involved had been agreed to by a fully informed and competent patient. If there was such an agreement, the complaint would not be acted upon¹⁶.

(Footnote continued from previous page.)

Judicial Affairs of the American Medical Association (1992), which is entitled "Fees for Medical Services". The Opinion states as follows:

A Physician should not charge or collect an illegal or excessive fee. For example, an illegal fee occurs when a physician accepts an assignment as full payment for services rendered to a Medicare patient and then bills the patient for an additional amount. A fee is excessive when after review of the facts a person knowledgeable as to current charges made by physicians would be left with a definite and firm conviction that the fee is in excess of a reasonable fee. Factors to be considered as guides in determining the reasonableness of a fee include the following:

- A. the difficulty and/or uniqueness of the services performed and the time, skill and experience required;*
- B. the fee customarily charged in the locality for similar physician services;*
- C. the amount of the charges involved;*
- D. the quality of performance;*
- E. the nature and length of the professional relationship with the patient; and*
- F. the experience, reputation and ability of the physician in performing the kind of services involved.*

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FTC staff has asked what the effect of a prior agreement between the physician and patient would be if the patient subsequently alleged a fee to involve fee gouging. If the patient was fully aware of what other physicians were charging for the services when the agreement was entered, and if the patient was not misled about some other factor which might lead a reasonable person to pay more than the market rate for a service, then the patient would be viewed as not having a valid complaint and the fee would not involve gouging. However, if the patient was not aware of the market rate, or was misled into believing that the presence of another factor warranted paying substantially more than the market rate, then the patient would be viewed as having a valid complaint

All level I complaints would be referred for mediation by the PGC. Level II complaints are those involving egregious conduct. The underlying patient or payer grievances in level II complaints would go through mediation for the purpose of resolving the complaints. However, level II complaints would also be referred to a PDC to evaluate whether the physician involved should be disciplined.

During mediation of complaints, each party would express views about the fee involved and any other conduct which gave rise to the complaint. The panel would express opinions about the reasonableness of the fee charged and the appropriateness of any other behavior at issue. Panel opinions would be based on their own expertise and experience in view of the circumstances of the complaint. The panel would consider the nature of the services performed, the difficulty of providing the services to the patient involved, any unusual problems or complexities that had to be managed, and other factors.

The opinions of the panel about the fee could be supplemented with other information about fees obtained from payer data bases, government fee schedules, academic studies, and the opinions of similarly situated physicians sought out by the panel. However, the medical society involved would not collect and maintain its own information about fees charged by physicians in its jurisdiction for use as a benchmark. Likewise, opinions of the panel about any other behavior of the physician involved could be supplemented by ethical codes and ethical opinions, articles about physician ethics, academic studies about the effects of certain conduct, and other materials. The object of the process would be to allow each side to gain an appreciation for the perspective of the other, and to be educated about the legitimate expectations of each party in the physician-patient relationship.

The goal of mediation would be to arrive at a settlement between the physician and the complaining party. No person, including the physician, would be required to agree to a settlement. However, participation in mediation by member physicians would be mandatory, and failure to cooperate with mediation would be grounds for discipline. Refusal to enter a settlement by a physician would not constitute lack of cooperation. Participation by the complaining party would be voluntary.

Settlements would not be limited to fee adjustments. The PGC could suggest, and the physician might agree to, other undertakings by the physician. These would be nonprice undertakings designed to educate physicians about how to prevent the type of incidents that give rise to patient complaints. These include how to manage the physician's office in ways that are considerate of the needs and interests of patients, how to communicate with patients, how to

manage billing procedures so as to prevent errors, and other issues. For example, if repeated complaints about a physician are found to result from coding errors on claims forms, then education about coding may be appropriate.

If warranted, the PGC could require a physician to engage in a nonprice undertaking designed to prevent future complaints or misconduct. While these undertakings might arise out of mediation of the fee dispute, they would be directed towards nonprice issues that came to light during review of the complaint.

Proceedings during mediation would be kept confidential. No part of the proceedings would be open to the membership or the public. The report of the initial investigation would be kept confidential, and any record created or documents collected would also not be disclosed. Likewise, any settlement reached, including settlements that are conditioned on nonprice undertakings, would not be disclosed to the membership or to the public.

PDCs would review level II complaints to determine whether the physician should be disciplined. The procedures specified by HCQIA would be followed to ensure fairness to the physician charged with unethical conduct. Participation in the PDC proceeding would be mandatory for the physician involved.

PDCs would keep their proceedings confidential. However, PDC decisions would be publicly disclosed. No information about the fee levels involved in a discipline for fee gouging would be disclosed, but the occurrence of the discipline would be made public. The purpose of disclosure would be to inform the public about the discipline.

The FTC Guidelines for Professional Peer Review of Fees

FTC staff have noted that, properly managed, professional peer review of physician fees results in three procompetitive benefits.¹⁷ First, it is a means of providing information to patients about physician fees and other issues. That is procompetitive because the information allows the patient to decide whether a fee is excessive in relation to those charged by other physicians. It is an important benefit because there are often wide disparities in fee information between patients and health care providers.

Second, fee peer review can be an efficient and low cost method for resolving disputes about fees between physicians, patients, and payers. That is procompetitive because it facilitates the expedient and fair resolution of disputed transactions. At present, there is no effective forum available to

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See Horosnak and See Rule at fn 4, supra

resolve disputes. Courts are expensive and difficult to use, and they are often very slow. State licensing boards are not designed to resolve individual disputes. Instead, they investigate physicians in response to complaints. At present, most licensing boards have sufficient resources to investigate only the most serious complaints.¹⁸

Third and finally, fee peer review builds confidence in the market for physician services. Patients develop confidence because they believe that they will be treated fairly, and that they will receive objective information in the event of a dispute.

However, an improperly managed fee peer review program can be anticompetitive and violate the antitrust laws. FTC advisory opinions note that antitrust violations may occur if fee peer review becomes a device to coerce physicians to adhere to certain fee levels or to coerce payers into accepting fee levels, if it is used to discipline physicians who engage in legitimate competitive activities or innovative practices that are frowned upon by other practitioners, or if it becomes a vehicle for physicians to agree among themselves about fee levels.¹⁹

The advisory opinions note that antitrust violations can be avoided if all concerned parties view fee peer review solely as a means of mediating specific fee disputes, rather than a process for the collective sanctioning of fee levels or particular practices. Mediation involves the expression of opinion by peer review panel members about a fee charged for a particular service provided to a patient. That expression of opinion allows the patient or payer involved to decide whether to pay the fee in question.

Certain guidelines designed to prevent anticompetitive abuse of fee peer review can be drawn from the FTC advisory opinions. These guidelines can be summarized as follows:

- (1) Participation in professional peer review of fees is voluntary for the physicians and any complaining or affected party, such as the patient. The FTC is concerned that proffered guidance in fee peer review could become coercive if the process is not voluntary.
- (2) Determinations made by the peer reviewers about the physician's fees are advisory, and have no coercive aspects. The FTC is concerned that coercive determinations could threaten independent pricing.

¹⁸ "State Medical Boards and Medical Discipline," Inspector General, Department of Health and Human Services (August 1990)

¹⁹ See Advisory Opinions cited at fn. 3, supra

- (3) Peer review decisions about fees are based solely on the facts and circumstances of the particular case. The FTC is concerned that independent pricing could be threatened if determinations about particular past prices become generalized in future fee peer review opinions.
- (4) Peer review decisions about the appropriateness of fees are kept confidential and are not disclosed except to the physician and complaining patient or payer. The FTC believes that dissemination of peer review opinions about fees could threaten independent pricing.²⁰
- (5) The association of physicians sponsoring professional peer review of fees does not collect information on fees charged by its members and does not use the information to establish a pricing benchmark. The FTC believes that the difficulty and complexity of a procedure should be evaluated based on the individual judgment and expertise of the peer reviewers. To the extent that any reference is made to external factors or benchmarks, consideration should be limited to fee information not sponsored or sanctioned by the medical society.

For the most part, the procedures proposed by the AMA would adhere to these guidelines, but there would be some significant departures. In particular, the proposed process would not be voluntary in all respects. The emphasis of the program would be mediation, but participation would be mandatory for members. Participation would be required because the public would not be well served by a peer review process that members could ignore when patients file complaints about them.

For the same reasons, the program would be coercive in some situations. Medical societies would discipline members who engaged in egregious fee gouging. The purpose would be to give the public confidence that physicians who engage in egregious fee gouging will be held accountable.

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The AMA understands that confidentiality is limited to information about the fee level itself as opposed to the fact of a peer review action. The AMA believes that medical societies may publicize information about the number and nature of peer review actions taken, and could publicize the names of individuals disciplined for fee gouging, provided that the fee amounts involved were not disclosed.

The AMA's Proposed Procedures For
Peer Review of Fees are Procompetitive

The judicial decisions relevant to peer review of fees are generally consistent with the current policy of the Commission in that they would permit self-regulation activities that do not constitute or enforce a price-fixing agreement. The AMA's proposed procedures for peer review of fees would clearly fall within the range of conduct deemed reasonable by the courts, and any departures from existing FTC guidelines would be procompetitive and lawful.

The Supreme Court has held that an agreement affecting price should only be condemned after a "quick look" to determine whether it has clear anticompetitive consequences and lacks any redeeming virtue. Broadcast Music, Inc. v. Columbia Broadcasting System, Inc., 441 U.S. 1, 19-20 (1979). As noted above, the Commission recognizes the procompetitive benefits that result from peer review of fees. The AMA's proposed fee peer review is thus not inherently suspect; it presents antitrust concerns only if the fee peer review serves to establish or enforce a price-fixing agreement.

The AMA's proposed process contains several elements designed to assure that the peer review conducted will not establish or enforce a price-fixing agreement. First, the PDCs will act on a complaint of alleged fee gouging only (1) when the complaint originates with a patient, or (2) when the complaint originates with another physician and the patient states that he or she either did not agree to pay the high fee, or would not have agreed to pay a fee that was extraordinarily high in comparison to those charged by comparable physicians. Only in extreme circumstances, such as where there is evidence of fraud or a mentally impaired patient, would a PDC pursue fee peer review when the patient is satisfied with the fee charged. This policy limits the possibility that a fee peer review action will be undertaken for the purpose of enforcing a price-fixing agreement among physicians. It would also focus fee peer review activity on those cases in which an imperfect information exchange between physicians and patients has created a distortion in the market which the physician has used to his or her financial advantage.

Second, PDCs will not develop any formal or informal benchmark schedule of reasonable fees with which to resolve fee disputes. Each allegation of fee gouging will be addressed under the unique circumstances in which it arose, and the PDC will simply determine whether the fee charged in that case was excessive. Third, there will be no public disclosure of any fee amounts determined to be excessive, or of the PDC's view of the reasonable fee in each case. These latter two elements limit the possibility that fee peer review will facilitate the development of a price-fixing agreement by physicians.

The Commission has expressed its concern that fee peer review may be used improperly to discipline physicians who compete by offering a new product or service. The substantial due process procedures contained in the AMA's proposal are intended to lessen the possibility of exclusionary conduct in

guise of peer review. The courts recognize that industry self-regulation is usually found lawful when such procedural safeguards are employed. Allied Tube & Conduit Corp. v. Indian Head Inc., 486 U.S. 492 (1988); Silver v. New York Stock Exchange, 373 U.S. 341, 364-67 (1963).

Finally, the Supreme Court's decision in Arizona v. Maricopa County Medical Society, 457 U.S. 332 (1982), is not inconsistent with the AMA's proposed process. In Maricopa, the physicians clearly agreed to limit their charges to patients who contracted with a particular insurer. The AMA's proposal involves no such agreement affecting price, and fee peer review is not likely to result in price-fixing. The courts have noted that if an ethical rule is not itself illegal, neither is enforcement of the rule. See, e.g., Vogel v. American Society of Appraisers, 744 F.2d 598 (7th Cir. 1984).

The AMA's proposed procedures for peer review of fees generally adhere to the guidelines developed by the FTC for a procompetitive fee peer review program. The limited ways in which the proposed procedures depart from the FTC guidelines are designed to make enforcement of the ethical rule against fee gouging more effective in a procompetitive manner. These departures actually reinforce the core concepts underlying the FTC guidelines and will not have any anticompetitive effects.

The departures from FTC guidelines in the AMA proposed procedures are as follows:

- Participation in fee peer review by members is mandatory.
- Members who engage in egregious conduct, including fee gouging, may be disciplined.
- Discipline for egregious conduct will not be kept confidential.

Each one of these departures will be discussed below.

a. Mandatory Participation Of Members In Fee Peer Review and Mediation

A primary procompetitive benefit of fee peer review is to provide information to the patient about physician fees and charges. The process helps reduce the disparity of information between physicians and patients. The information helps the patient decide whether to pay all or a portion of the fee in question, and whether to patronize other physicians.²¹

Mandatory participation in fee peer review by medical society members improves the information made available to the patient during mediation. A physician

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Hoschak, supra, footnote 4

who cooperates with the PGC will provide patient records and other documents, will discuss the physician's perspective about the patient's treatment, and will explain the reasons for the fee. There will be a much better basis upon which to judge whether the fee was reasonable, whether the physician made any mistakes in billing, whether there was a foundation for nonprice complaints by the patient, and other matters.

In addition, the physician receives information from the patient that may help the physician operate a more competitive practice. The physician may find out about office management problems that need to be corrected, about office staff that are not interacting well with patients, or about problems that the physician has in communicating with patients. In addition, the PGC can help inform the physician about educational programs that can help correct the problems revealed during mediation.

Finally, mandatory participation increases the likelihood that settlements acceptable to the patient and the physician can be arrived at. Satisfactory settlements build confidence in the market for physician services. Patients develop confidence that they will be treated fairly, and that they can have complaints resolved.

Mandatory participation in PGC proceedings is not anticompetitive because the focus is on mediation. The only requirement is that the physician participate, not that the physician adhere to any fee or fees recommended by a PGC or the medical society. Further, the physician is not subject to discipline by the PGC for fees charged. (Mandatory participation in disciplinary proceedings conducted by the PDC is discussed below). Participation in remedial education may be required, but only for nonfee aspects of the physician's practice.

b. Disciplines for Fee Gouging

The possibility of PDC discipline for egregious conduct is procompetitive. It provides the patient with information about physicians who have engaged in unconscionable fee gouging or other misconduct. That allows the patient involved and other patients to decide whether or not to continue dealing with the physician. In addition, it builds confidence in the market because patients know that physicians who engage in egregious conduct can be held accountable.

Discipline for fee gouging is not anticompetitive. In most situations, the complaint about an egregious fee will arise out of nonprice conduct such as fraud, the provision of inappropriate services, the provision of substandard services, or other misconduct. Disciplinary actions that are primarily based on such misconduct do not reflect a maximum price fixing agreement.

Even if the discipline concerns fee gouging only, it will not likely reflect maximum price-fixing. Patients who complain about being gouged normally have not agreed, with full information about comparable fees and the quality and need of the service being offered, to pay a fee that is extraordinarily high. Such a patient normally will not have been informed about the extraordinary nature of the fee before receiving the service and, if so informed, would not have agreed to it in advance. Therefore, these are transactions that would not have occurred but for disparities in information between the physician and the patient.

It is unlikely that a patient who, for whatever reason, agreed to an extraordinarily high fee while being fully aware of the fees charged by comparable physicians will file a complaint. Such incidents are likely to be few, and the PDC will address them only in extreme circumstances.

The colleagues of a physician who charges extraordinarily high fees may complain to the applicable medical society. Disciplinary actions that result from a physician complaint about another physician's high fees might reflect enforcement of a maximum price-fixing agreement. However, as discussed above, that possibility can be remedied by restricting discipline to situations where there are patient complaints. If a physician complains about a colleague who charges extraordinarily high fees, a PGC would investigate to determine whether the physician's patients were fully informed and agreed to pay the fee without being subject to undue influence. If the patients were generally satisfied, there would be no grounds for discipline.

c. Disclosure of Discipline

Finally, publicly disclosing disciplinary actions for fee gouging is procompetitive. It provides information to consumers about physicians who have been charging extraordinarily high fees in situations that have been unfair to patients. That helps patients decide which physicians to patronize, and it builds confidence in the market for physician services.

Moreover, public disclosure of disciplinary actions provides a deterrent effect among the physician community and increases the effectiveness of enforcement of the profession's ethical code.

No information would be disclosed about the fees charged by the physician disciplined or the fees considered reasonable by the PDC. Therefore, disclosure would not constitute a signal about the fee levels that could facilitate a physician fee agreement on fees.

d. Effect on Health Care Expenditures

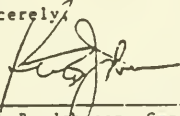
FTC staff has asked whether the proposed procedures for professional fee peer review will reduce health care expenditures. The AMA cannot promise that precisely discernible savings will result that will be directly attributable to the procedures, but the AMA and the CMS expect that the procedures will help control health care costs. As stated earlier, the program is designed and intended to comply with the antitrust laws and therefore will emphasize the mediation of fee disputes. The program will not, and cannot under the law, be a fee control program which could result in precisely discernible and quantifiable savings. It is expected that the program will reduce the incidence of fee gouging, and therefore result in some directly attributable savings, but fee gouging is not common and its elimination is not expected to result in substantial savings overall. It is expected that the program will help detect and reduce the incidence of fraud, which should also result in cost reductions.

In addition, the information provided to patients through the peer review process will enable them to compare physician fees more effectively, and it will give them a better understanding of medical practice and medical decision making that should make them more effective consumers. The process should also help patients develop a better understanding of what benefits are realistic to expect from physicians, and the extent of the resources that are necessary to provide effective health care. Also, physicians will become more sensitive to the complaints of patients and will change their practice patterns to respond to them. The result of more informed consumers and more sensitive physicians should be an improved market.

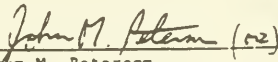
Conclusion

For the reasons stated above, the AMA and CMS believe that the AMA's proposed fee peer review procedures will be procompetitive and facilitate the operation of the market for physician services. Equally important, the procedures will enhance the protection of patients where the market does not operate efficiently and thereby increase the trust of patients in their physicians, which is the heart of the physician/patient relationship. The AMA and CMS request an opinion that the proposed procedures are not anticompetitive and would not be subject to FTC enforcement actions.

Sincerely,



Kirk E. Johnson, General Counsel
Edward Hinchfeld
American Medical Association



John M. Peterson (cz)
John M. Peterson
Howe & Hutton, Ltd.
Counsel for Chicago Medical Society

Mr. SCHUMER. Do you agree this is a very serious problem that has not gotten enough attention from law enforcement or our Government in general. Would you agree with that?

Dr. SCHENKEN. Yes, Mr. Chairman.

Mr. SCHUMER. Then we start out from the same place.

Second, I understand physicians' concern about nonintentional errors creating criminal problems. Do you know examples?

Dr. SCHENKEN. Certainly. I can give an example in my own medical practice. I run a large medical laboratory in Omaha, NE, and we serve Iowa, Missouri, and Nebraska. We perform hundreds of thousands of tests, probably a thousand different code numbers. They are constantly changing, RV, RVS, on and on. We are beholden to computers absolutely. It sometimes takes us a little time to ferret out these computer errors. Humans are not 100 percent.

Mr. SCHUMER. That is abuse. That is not fraud. I understand the fear, and it should be there. But I would like to know examples of where physicians were indicted, convicted or not, for things that were not intentional.

Dr. SCHENKEN. Mr. Chairman, I know of none in which they were indicted.

However, we have many instances in which our members complain that investigators from Medicare and others are implying that their activities have been fraudulent which, when we look into it, at best it is a debate over how you coded a particular item for services clearly provided and clearly indicated.

Mr. SCHUMER. I understand that. You would like the intent definition tightened, made stronger?

Dr. SCHENKEN. Yes, sir.

Mr. SCHUMER. There are two sides to the coin, obviously.

Dr. SCHENKEN. We understand that.

Mr. SCHUMER. The scoundrels will say we didn't have intent for this.

It seems to me in light of your answer to the last question that the pendulum may need strengthening in the other direction rather than the direction in which you seek. I have had lots of physicians complain to me, and most of them are not complaining about criminal prosecution. They are complaining about regulators coming in and second-guessing judgments on medical questions.

Dr. SCHENKEN. That is right.

Mr. SCHUMER. That is something I can understand.

Just give me succinctly as you can your best argument why, at this point in time where so much fraud is not caught or prosecuted, that we should make it even more difficult to catch those engaged in fraud by raising the intent standard. It might safeguard others some innocents caught in the net, but you don't have a long list of people like that.

Dr. SCHENKEN. Mr. Chairman, one of your panel members, I think Mr. Schiff, asked Dr. Marr the question about the intent. His answer was, as mine has to be in part, I am not an attorney, so the details I am a little concerned about, but his answer in part is, at least when a pattern of abuse or malfeasance comes up we look after it.

In general, as a nonlawyer physician, I absolutely agree with that. What we would like to do—in response to Mr. Schiff and your

request, it would probably be better for attorneys from the AMA to work with your committee members to be sure the language meets most of our goals because I'll guarantee you our goals are, if I can partially read your mind, the same. Every doctor in the country is hurt by what happens in the newspapers over the operations of the few.

Mr. SCHUMER. Dealing with the S&L crisis on the Banking Committee, it was amazing to me how good S&L's—this is before the crisis erupted—would run to protection of the bad ones for solidarity or other reasons. I would plead with the AMA, with its considerable weight and clout, not to do that.

Just one other thing to bring back to your board before I conclude. I think to get any strengthening of the intent provisions we would have to see specific examples of abuse, not just the fear of it out there.

Dr. SCHENKEN. Certainly.

Mr. SCHUMER. Mr. Ramstad.

Mr. RAMSTAD. Thank you, Mr. Chairman.

Dr. Schenken, in your testimony you suggested the possibility of Federal grants to medical societies for these programs for investigations and so forth. Money is tight around here these days. I wonder, it seems to me, isn't that the charge of medical societies and shouldn't medical societies perhaps be doing more self-policing?

Dr. SCHENKEN. Mr. Ramstad, the answer is yes. Can I divide the question?

Mr. RAMSTAD. Please.

Dr. SCHENKEN. First of all, the issue of Federal grant possibilities. That would be the availability of money and clarity of new programs that we would propose and so forth. So, yes, we would like you to consider it but focus on what it might be.

The other issue, medical societies have felt for years that one of their obligations to the public is to assure the public through their own disciplinary actions that the profession is holding itself out to be providers of good quality, caring medical services.

Unfortunately, actions in the last two decades by the Federal Trade Commission and the Justice Department have prevented our medical societies from getting into this narrow but critical area. Have we provided our letter to the Federal Trade Commission to the committee? Yes, I am told we have.

We petitioned for several years to give us the waiver to do that. If we do that, it won't require additional expenditures of money. Yes, we can, but if it gets to investigations on our part we will have the same problems as the last panel.

We don't have folks—our doctors have to go back to their office and take care of patients, so we don't have the time to do the actual investigation or the expertise, Mr. Ramstad.

Mr. RAMSTAD. Just a followup if I may.

Mr. SCHUMER. Please.

Mr. RAMSTAD. Dr. Schenken—and I have not seen the letter. I will certainly get that. But would the changes, to change the status quo, would that require legislation or would that be done through rulemaking of the respective agencies?

Dr. SCHENKEN. I believe it is administrative.

Mr. RAMSTAD. Administrative law changes.

Mr. SCHUMER. Either one. We could overrule the agency by legislation.

Dr. SCHENKEN. Do the best you can to help us.

Mr. RAMSTAD. Thank you, Mr. Chairman.

Mr. SCHUMER. Mr. Edwards.

Mr. EDWARDS. Thank you, Mr. Chairman.

A few years ago, Dr. Schenken, there was a problem of physicians engaging in malpractice and then getting in trouble with the local association but then going to another State. And there was no way for the other State or county, a few hundred miles away, to know that they had a scoundrel on their hands.

I think that through Congressman Henry Waxman's efforts there was Federal assistance in establishing a data bank with the proper privacy safeguards so that this data bank was established somewhere.

Now, for people—call them scoundrel doctors again, and I am sure there are not many but there must be some—who are engaged in this kind of fraud, it is not necessarily criminal but malpractice; would this same data bank be used?

Dr. SCHENKEN. Depending on what they were convicted of, I would say, yes, Mr. Edwards.

For the benefit of the rest of the committee, the AMA supported those efforts as they finally came down and they were finally developed.

But we also—the AMA has the largest data bank on physicians anywhere, and we offered to make that available. And, in addition, the AMA is cooperating with the Federation of State Medical Examining Boards, the 50 boards, and they are putting in place—it is in place now—a system to where this information is automatically sent to the other 49 states if there is a rule.

But in our testimony we have supported the concept of adding convictions and proof of that sort of thing to the information that can be distributed.

One other thing you might be interested in, Mr. Edwards. We are not going to do this without the help of the public. I think the chairman asked if the public phone would be valuable. We would agree with the answer. We have started a program—actually it turned out that it was in today's Post, which works out nicely. We started a program—

Mr. SCHUMER. AMA has power everywhere.

Dr. SCHENKEN. Yes. I wish we had as much as people think we do.

But to try to get the public in, to make things convenient for patients. And I have a son who is ill in the hospital as we speak, and I have become a parent looking at hospital bills, and I am very sympathetic to what you are talking about, Mr. Chairman, Mr. Edwards.

But the patients have got to help us and to make things convenient when we have electronic billing, bypass the patients, the bills go to the insurance companies, et cetera. And we really need to get some better way to have the patients look at the record of what has happened to them and inform their doctors if there are errors and inform us if there are mistakes.

It is too long an answer, but my answer is, yes, it should be done, and we think it is going to be done. But if more needs to be done we support it.

Mr. EDWARDS. Thank you. Your testimony is very helpful. Thank you, Doctor.

Mr. SCHUMER. Mr. Ramstad.

Mr. RAMSTAD. Just briefly, Mr. Chairman. I know the hour is late.

I thank you, Dr. Schenken. I have a copy of the letter to which you referred, from the AMA's general counsel to Secretary Clark at the FTC, dated April 30, 1992, concerning the AMA's proposed peer review procedures. I commend the AMA for this initiative and hope that the FTC gives it serious consideration. If not, it seems to me that legislation would be appropriate as the chairman alluded.

My question—Mr. Chairman, I assume this is part of today's record, this letter?

Mr. SCHUMER. Yes, it is. Without objection.

We have a statement, which I didn't add earlier, of Congressman Pete Stark who is our colleague from the Health Subcommittee of Ways and Means, and, without objection, I will add that to the record as well.

Mr. RAMSTAD. Thank you, Mr. Chairman.

[The prepared statement of Mr. Stark follows:]

PREPARED STATEMENT OF HON. PETE FORTNEY STARK, A
REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Mr. Chairman, Members of the Committee:

Thank you for focusing more attention on the need for cutting fraud, waste, and abuse and improving the management integrity and control over health care programs.

It is estimated that the fraud, waste, and abuse in the nation's \$900 billion health sector may run as high as 10%, or \$90 billion. If we could find that kind of savings, it would be enough to provide health insurance to all the nation's un- and under-insured. Of course, we all know that there is no line-item marked

"Fraud, waste, and abuse...\$90,000,000,000...please cut here"

Studies by the GAO reported in testimony before the Ways and Means Subcommittee on Health have made it clear that the Federal government actually does a better job than the private sector in rooting out fraud and stopping abusive practices. The nation's 1100 or so insurance companies and the tens of thousands of self-insured plans are simply unable to match the biggest cop on the beat--the Federal government. Even so, the Federal government could do more and should do better. Increasing the budget of the HHS Inspector General would be a good start.

But the best thing we could do would be to apply the Federal government's anti-fraud rules and tools to the entire health sector of the economy. That's what my bill, The Health Care Cost Containment and Reform Act of 1993, HR 200, does. (It includes the same strong anti-fraud provisions as were reported by the Health Subcommittee last July 1.) I urge your support of this legislation.

But we must also recognize that the larger problem lies in the fact that both the public and private sectors often pay way too much for various medical procedures, medicines, and devices. This gross

overpayment results in irresistible temptations to cheat: to over-utilize, to over-test, to over-medicate. For example, Medicare pays in the \$400 to \$600 range for an MRI. The private sector frequently still pays \$1100 for an MRI image! Medicare still pays too much. The real cost of an MRI is probably somewhere in the \$350 range in a well-run, well-utilized facility. With today's profits, many providers are seduced into over-ordering MRIs.

A recent FBI conference on health care fraud commented on some home IV and infusion therapy providers. These companies bill private pay patients \$10,000 a month for products that cost only \$1500. With this kind of 'easy' profit, it is little wonder that medical judgment becomes distorted.

While we should increase the number of policemen in the health care sector, we can never do enough given these excessive payments. And it reminds me of the line from the Declaration of Independence, "he has erected a multitude of New Offices, and sent hither swarms of Officers to harrass our people, and eat out their substance."

There has to be a better way. There has to be a better way than erecting more PROs and second-guessers looking over every doctor's shoulder.

The better way is to fundamentally reform the health care system. Currently, the health sector has an open door to the nation's Treasury and private pocketbooks. Only by putting Medicare type reimbursement limits on all sectors of the health economy (allowing them to inflate for the growth in the economy) will we bring some restraint to excessive profits and health care abuses. Only by taking the fat out of the reimbursement system can we abate the fever of get-rich-quick-greed that has infected the healing professions.

Mr. Chairman, I hope you and your Subcommittee will support the anti-fraud provisions of HR 200. But it is important that you also support fundamental systems reform. We must fix the bleeding artery, not just satisfy ourselves with fixing the capillaries.

Dr. SCHENKEN. Could I take 30 seconds?

Mr. SCHUMER. Please.

Dr. SCHENKEN. I am going to be retiring now. I was working in the ethics area, and I served for 5 years in that capacity.

We received a complaint from a patient who had a 1-inch cut on the back of their hand, 1 inch. I got 1-inch cuts on the back of my hand when I played baseball, and I used to put a piece of tape on them and go home, as many of you did.

The patient did not complain because the physician charged \$4,500 to suture that 1-inch cut. The patient complained because the insurance company only paid \$2,900.

I checked around home and it was more than a 1-inch cut, it had cut a tendon, so it was a little more complicated than that. But the orthopedic surgeons in Omaha told me—this is not from Omaha, by the way—but that \$600, \$800, maybe \$1,000, would be a maximum. I was unable to do anything more than mail that complaint on to the next society.

And, fortunately, those complaints are rare, but we could have done something about that complaint, and any help you could give us would be greatly appreciated.

Mr. SCHUMER. We will certainly look into it, Dr. Schenken. Thank you.

Dr. SCHENKEN. Thank you.

Mr. SCHUMER. Now we will hear from our fourth and final panel if they would come forward.

Our fourth panel today includes members of the insurance industry who obviously must deal with the issue of health care fraud. William J. Mahon is executive director of the National Health Care Anti-Fraud Association, NHCAA. His association, formed 8 years ago, is headquartered here in Washington. Their effort is aimed at helping both the public and private insurance sectors detect, investigate, and prosecute fraud on our health care system. In addition to his work in the insurance industry, Mr. Mahon has worked as a journalist, covering financial and legal issues.

Our second panelist is Joyce L. Hansen. She is the director of claim support services for the Northwestern National Life Insurance Co. based in Minneapolis, MN, and she spent 15 years working in the insurance industry in addition to setting up a special investigations unit within her company. She has also helped to found the Midwest Insurance Fraud Prevention Association. She is on the board of governors and the executive committee of the NHCAA.

I want to thank each of you for coming. I want to recognize Mr. Ramstad to say a few words of welcome to you, Ms. Hansen. You hail from the same area. Then we will go right to Mr. Mahon.

Without objection, your entire statements will be read into the record, and you may proceed as you wish as soon as Mr. Ramstad does his thing.

Mr. RAMSTAD. Thank you, Mr. Chairman.

I would just like to personally welcome Ms. Joyce Hansen to the hearing. We come from the same hometown of Minnetonka, MN. Her reputation in this area is known throughout the State, and indeed the country. I thank you for your patience in waiting as a member of the last panel, certainly. In fact, she is now president,

I believe, of the Midwest Insurance Fraud Prevention Association. Is that correct?

Ms. HANSEN. That is correct.

Mr. RAMSTAD. And started Northwestern National's fraud program in 1985. We are certainly glad to have you here today and appreciate you coming to Washington to present your testimony.

Ms. HANSEN. Thank you, Mr. Ramstad.

Mr. RAMSTAD. Thank you.

Mr. SCHUMER. Go ahead. Why don't we start with Ms. Hansen, then we will go to Mr. Mahon, since she just received such a nice encomium from Mr. Ramstad.

STATEMENT OF JOYCE L. HANSEN, DIRECTOR, CLAIM SUPPORT SERVICES, NORTHWESTERN NATIONAL LIFE INSURANCE CO.

Ms. HANSEN. Good afternoon. I am Joyce Hansen, director of claim support services, Northwestern National Life Insurance Co. I will refer to it as NWNL. I appreciate the opportunity to appear before you today on this important subject matter for NWNL, the private health insurance industry, as well as all consumers of health insurance products.

Northwestern National Life Insurance Co. is headquartered in Minneapolis. We have been in the insurance business since 1885. The NWNL companies employ 2,200 people around the country.

I am an employee of NWNL's Employee Benefits Division. I have been with NWNL for 9 years. I started the fraud program in 1985, becoming the first special investigator in the employee benefits division. We concentrate on provider and claimant fraud investigations. Today we have five full-time special investigators.

In 1990, I was instrumental in the formation of a regional fraud prevention association and currently serve as president. The Midwest Insurance Fraud Prevention Association draws insurance representatives in health, life and disability markets from Minnesota, Wisconsin, and North Dakota.

Also in 1990, NWNL became a corporate member of the National Health Care Anti-Fraud Association. This association has furthered our commitment to improve the detection, prevention, and prosecution of health care fraud.

One of the goals of NHCAA is to be able to share information amongst the corporate members which, in turn, makes fraud investigations much more effective. I will briefly summarize the nature and variety of health care fraud in the industry as seen from the private sector.

The sources of fraud and abuse in the health care field come from a variety of places which include providers, such as physicians and hospitals, suppliers of medical devices, home health care agencies, laboratories, pharmacies, mental health facilities, as well as insureds. The focus of my testimony is on provider fraud, which we believe constitutes a much larger dollar amount.

Let me emphasize that in our experience, the majority of providers are honest people. We are not after providers or facilities that make occasional billing errors. We are concerned about those who make concentrated, intentional attempts to abuse the system or bend the rules for financial gain.

It can take months, sometimes years to uncover fraud schemes. Schemes range from the simplistic to the complex. We have 600 people around the country that examine claims for NWNL. We process 15,000 claims a day in 8 claims centers that are located all across the country. We rely on these claims examiners to detect suspicious claim submissions.

As the schemes get more sophisticated and complex, the ability to detect these schemes up front becomes much more challenging. Some of the fraud techniques we see are physicians who claim to have treated many more patients than he or she could possibly see in a given time, labs which churn out an unusually large number of tests, billing for services not rendered, altered or fabricated bills submitted by providers, accepting insurance coverage as full payment and waiving the coinsurance and deductible, and unbundling or fragmenting bills.

Dr. Myer talked about the unbundling a little while ago. An example I would give is a surgeon may code for a hysterectomy as a number of separate procedures, exploration of the abdomen, removal of the ovaries and tubes and removal of scar tissue. Doing so brings in thousands more.

Professional offices which have a tax ID number and may be licensed to operate in that jurisdiction but may not have a licensed provider actually rendering the services and double billing. Keep in mind that this list is certainly not all inclusive. New and different schemes appear frequently, and it is a challenge to keep abreast of the activity.

Another challenge that we will soon be faced with is the detection of suspicious activity with electronically submitted claims. The investigation of fraud takes a united effort of participants from the public and private side.

It is time to send a message to perpetrators that insurance fraud will not be tolerated. It is now crucial to control the ever spiraling costs in our health care system. One of the most direct ways to bring down health insurance costs is to eliminate as much fraud as possible from the system.

The case summaries included in my prepared testimony show examples of different fraud schemes ranging from alteration of claim forms, billing for more therapy sessions than possible in a given time period, billing for services not rendered, to forgiveness of copayment and overutilization.

Everyone has resource problems when it comes to the investigation and prosecution of health care fraud. As we get law enforcement more interested in the pursuit of health care fraud, we can cooperatively build bigger and better investigations.

Thank you very much for the opportunity to speak before you today, and I would be happy to answer any questions you may have.

Mr. SCHUMER. Thank you, Ms. Hansen.

[The prepared statement of Ms. Hansen follows:]

PREPARED STATEMENT OF JOYCE L. HANSEN, DIRECTOR, CLAIM SUPPORT SERVICES, NORTHWESTERN NATIONAL LIFE INSURANCE CO.

Before the Subcommittee on Crime and Criminal Justice of the House Judiciary Committee

February 4, 1993

Good Morning, I am Joyce Hansen, Director of Claim Support Services, Northwestern National Life Insurance Company (NWNL). I appreciate the opportunity to appear before you today on this important subject matter for the insurance industry as well as every consumer of health insurance products.

Northwestern National Life Insurance Company is headquartered in Minneapolis and has been in the insurance business since 1885. The NWNL Companies employ 2,225 people around the country. I am an employee of NWNL's Employee Benefits Division. The division provides products and services that include life, health, disability, long term care insurance, claim administration, and national and regional managed care programs. Today the company's Employee Benefits Division has more than 3,250 group policies and contracts in force. Our market concentration is on groups of 250-5,000 lives.

I have been with NWNL for 9 years. I started the fraud program in 1985 becoming the first special investigator in the Employee Benefits Division. We concentrate on provider and claimant (or insured) fraud investigations. Today we have 5 full time special investigators. Our goal is to prevent fraud through the education of claim examiners and insureds by aggressively pursuing suspected fraud by providers and claimants.

In 1990, I was instrumental in the formation of a regional fraud prevention association. The Midwest Insurance Fraud Prevention Association draws insurance representatives in health, life and disability markets from Minnesota, Wisconsin, and North Dakota. We hold quarterly meetings to learn about insurance fraud investigation techniques, to network on a regional basis and to involve regional law enforcement personnel in our activities. I am currently President of the Association.

Also in 1990, NWNL became a corporate member of the National Health Care Anti-Fraud Association. This association has furthered our commitment to improve the detection, prevention, and prosecution of health care fraud. The NHCAA, with members representing both the private and public sector plays a critical role in public education and in directing the resources of the insurance industry against fraud. One of the goals of the NHCAA is to be able to share information amongst the corporate members which in turn makes fraud investigations much more effective.

My discussion today will focus on:

- The nature and variety of health care fraud in the industry.
- Specific case examples illustrating various types of health care fraud.

The sources of fraud and abuse in the health care field come from a variety of places which include: providers such as physicians and hospitals, suppliers of medical devices, home health care agencies, laboratories, pharmacies and mental health facilities as well as insureds. The focus of this presentation is on provider fraud which we believe constitutes a much larger dollar amount.

Let me emphasize that in our experience the majority of providers are honest people. We're not after providers or facilities that make occasional billing errors. We're concerned about those who make concentrated, intentional attempts to abuse the system or bend the rules for financial gain.

One of the most notorious cases of health care fraud involves what has been called the "California Lab Scheme". Mobile testing vans were set up in the parking lots of health clubs and offered members free physicals.

When club members came in for the physical they were asked to give their name, policy number, insurance company, and medical history. Limited services were performed, all non-invasive techniques, and the member was told they were "fit".

A few months later their insurance company was billed for false claims for services not rendered and medically

unnecessary services resulting in thousands of dollars of charges. The insureds were not billed for any of the charges and the perpetrators of this fraud considered what ever the insurance company paid as "payment in full".

It can take months, sometimes years to uncover these frauds. This is because the claims come in one by one and it takes time before a pattern is noticed. Summarized below are a variety of health care fraud schemes perpetrated against private payors:

- Physicians who claim to have treated many more patients than he/she could possibly see in a given time.
- Labs which churn out an unusually large number of tests.
- Billing for services not rendered.
- Altered or fabricated bills submitted by providers. These may include routine services billed for on a Sunday, dates of service which are altered, or fluctuating prices for identical services on the same bill.
- Accepting insurance coverage as full payment and waiving the co-insurance and deductible amounts. The provider may overbill so that the total collection equals or exceeds the amount that would have been collected had the collection of the fee been made from the insurance company and patient. Quite often the patients are solicited which raises the question as to whether the treatment was for a needed medical service.
- Unbundling or fragmenting bills. This is a coding scheme in which the provider uses more codes than necessary for a group of procedures that are covered by a single Current Procedural Terminology (CPT-4) code. By splitting the procedure code into different parts, the provider attempts to collect a much higher reimbursement. For example, a provider will intentionally bill

for admit fees, discharge fees, and daily hospital care where the services are globally inclusive in the surgical procedure.

- Professional offices which have a tax I.D. number and may be licensed to "operate" in that jurisdiction, but might not have a licensed provider present providing services
- Double billing. Cases in which a husband and wife work for different firms with different insurance companies, and the provider bills both for the same procedure

Keep in mind that this list is certainly not all-inclusive. New and different schemes appear frequently and it is a challenge to keep abreast of the activity.

The investigation of fraud takes a united effort of participants from the public and private side. It is time to send a message to perpetrators that insurance fraud will not be tolerated. It is now crucial to control the ever spiraling costs in our health care system. One of the most direct ways to bring down health insurance costs is to eliminate as much fraud as possible from the system.

Summarized in the next section are specific fraud cases that NWNL has investigated

The names of the people involved have been changed to protect their identity. None of these cases have been prosecuted in a court of law.

Everyone has resource problems when it comes to the investigation and prosecution of health care fraud. As we get law enforcement more interested in the pursuit of health care fraud, we can cooperatively build bigger and better investigations. The chances are good that if providers are stealing from us they are more than likely stealing from everyone else.

CASE SUMMARY #1

This case involved an insured and his family who had group health coverage for only 20 days. This was due to a three month waiting period that the employer selected for eligibility under the group plan, and the fact that the insured terminated employment 20 days after he became eligible for coverage.

NWNL received numerous dental claims on the insured and his four dependents. The claims were assigned to the dentist and had been submitted by the dentist. "White out" had been used on all the claims to change the dates of service within the 20 day eligibility period. It is our belief that the dentist found out that the family only had a certain period of time they were eligible for coverage.

NWNL requested the dental treatment records and uncovered several more discrepancies in the dates of service

The claims were denied because of discrepancies in the billing.

\$3,000 was saved on these claims and the dentist sent us a letter stating he had settled with the insured for the charges due.

CASE SUMMARY #2

In January 1990, the patient, a young boy, was admitted to a hospital in Texas for psychological treatment. In March 1990 the patient was removed from the hospital by his family.

After noticing discrepancies in the bills concerning therapy charges, the insured inquired about the bills from the physicians office. The insured was informed that they were billed for 3 individual sessions plus 1 group session per week. The insured was also advised that the physician did not come to the hospital on weekends or go to the hospital every day. The insured questioned a charge of \$340.00 for 68 Lithium tablets. The insured found that 90 Lithium tablets could be purchased at the local drugstore for \$16.95. The insured reported that the bill reflects a \$50.00 charge for a family therapy session which they attended but in this session the family watched a film on Alcoholics Anonymous.

The investigation disclosed that for the 48 hours of inpatient care alone, NWNL was billed for 81 therapy sessions for a total amount of \$10,065.00. A review of the patient log maintained at the hospital and treatment records only documented the physician as seeing the patient 19 times. With the assistance of the insured plus the TX State Medical Board NWNL was able to obtain a refund of our overpayment. Through action by the Medical Board the physician also received three years probation and 10 hours of medical education plus a public reprimand.

CASE SUMMARY #3

Jon Doe of Louisiana complained of feeling depressed and desperate. He admitted to abusing drugs and acknowledged that he needed help.

Mr. Doe called an 800 number that offers help. Note, the 800 numbers are located in the business section of the telephone book under COCAINE.

Mr. Doe had a conversation with a person at the COCAINE hotline (call lasted approximately 15 minutes). He gave the hotline his insurance information. The hotline representative called him back some time later and told him that he is covered. The representative informed him that a pre-paid plane ticket will be provided for his transportation to California.

The patient is told that he is covered at 100%. Mr. Doe is concerned because he knew he had a \$300 deductible to satisfy. The representative told him that the cost of his deductibles and coinsurance or anything not considered eligible by his insurance will be picked up on a special "grant". Mr. Doe is told that these grants come from wealthy people that have been through the program and donated money to help other people.

Mr. Doe informed us that he did not see a doctor for the first three days. The first days were spent on administrative activities and basic tests.

Mr. Doe advised NWNL that he demanded to be released after eight days or he would leave on his own. He was informed that he needed to be kept longer. (His insurance covered 21 days and it is alleged that the facility would have kept him confined until his insurance ran out).

Most patients are not aware of the cost of the total confinement;

- \$14,000 for an 8 day stay
- \$57,000 for a 23 day stay
- \$76,000 for a 36 day stay

NWNL denied the claim. Further investigations are currently underway with similar allegations regarding treatment by this facility.

CASE SUMMARY #4

NWNL was alerted to follow the practices of this provider by a phone call from one of our insureds. She indicated that we had paid for services that had not been rendered.

This insured had been to a foot clinic in California on 6/24/91 and had various procedures done on her right foot. Total charges were \$2370 and this bill was processed. We then received and processed another bill for this insured for various procedures done on the left foot, date of service 7/8/91, total charges \$1923. When the insured received her explanation of benefits (EOB), she contacted NWNL indicating that she had not been seen on 7/8/91 nor had she had any surgeries done on her left foot. At this time the claims were referred to Special Investigations.

After 8 phone calls and various delays, we received a refund for the 7/8/91 claim but no explanation or reason for the additional billing.

Since the provider was flagged on our claim paying system in 1991, we have received claims on 11 other individuals totalling over \$25,000. Operative reports were received with each claim. The Op reports are all duplicate copies, with "blanks" left to be filled in. NWNL sent verification letters were sent to all insureds, and requests for treatment records were sent to the provider for most of these insureds. To date we have not received treatment records on any of the insureds. Most of the claims have been denied as the services cannot be verified by the insured and documentation has been received from the provider to substantiate the claims. All insureds who returned verification letters also indicated that insurance payment was accepted as payment in full. It is also interesting to note that the provider has not sent any rebuttals on any of the claims we have denied.

In this case, all of the insureds are Hispanic. It is possible that this provider is assuming that they will take no action upon receipt of their EOB's as they probably don't understand what is written.

A case is pending before the California Fraud Bureau and the information has been shared with NHCAA Corporation Members on a confidential basis.

Mr. SCHUMER. Mr. Mahon.

**STATEMENT OF WILLIAM J. MAHON, EXECUTIVE DIRECTOR,
NATIONAL HEALTH CARE ANTI-FRAUD ASSOCIATION**

Mr. MAHON. Thank you, Mr. Chairman.

We would commend you and your fellow members of the subcommittee for your attention to health care fraud. It is increasingly acknowledged to be a problem nationwide, a crime problem of genuinely alarming proportions, and we would also commend you on the type and the quality of the information that you are generating through this hearing today. I think all of the preceding witnesses have done a very good job of outlining the nature and the impact of the problem.

I would note that NHCAA is, in fact, a hybrid type of organization that is unique in that it combines the efforts of the antifraud specialists in the private health insurance side, the commercial insurers and Blue Cross/Blue Shield plans, with their counterparts in Federal and State law enforcement responsible for policing the health care payment systems. As such, we are not a trade association of the insurance industry; we are an issue-based cooperative organization that represents this combined effort.

Our objective, as Ms. Hansen said, has always been to improve our private and public sector members' ability to detect fraud, to investigate it, to prosecute it on the civil and the criminal fronts, and as a byproduct of those efforts, to prevent fraud along the way.

To profile the makeup for you a little bit, from the private sector NHCAA has 43 so-called corporate members from the commercial and not-for-profit insurance side. On the public sector side, the members of our board include the chief of white-collar crime at the Federal Bureau of Investigation, the Deputy Inspector General for Investigations—Mr. Morey from whom we heard—and his colleague, the Assistant Inspector General for Civil Monetary Penalties at the Office of Inspector General of HHS, also the assistant U.S. attorney who serves as Chief of the Civil Division in the Eastern District of Pennsylvania in Philadelphia, the director of the Florida State Medicaid Fraud Control Unit, the Medicaid fraud counsel of the National Association of those State Medicaid Fraud Control Units, and as of last week, the Deputy Director of the Office of Medicare Benefits Administration in the Bureau of Program Operations at the Health Care Financing Administration, who is directly responsible for monitoring and coordinating HCFA's fraud and abuse detection and deterrence program.

Beyond that organizational membership and representation, NHCAA also has 480 individual members who are drawn from the ranks of those members as well as from nonmember insurance companies and from a very wide variety of other State and Federal law enforcement agencies. Virtually any organization with enforcement responsibility is represented. The Defense Criminal Investigative Service responsible for CHAMPUS fraud, the Office of Personnel Management which investigates fraud in the Federal Employees Health Benefits Program, the Postal Inspection Service, and many States' attorneys general offices.

We pursue our overall objective in a variety of ways. We serve as a vehicle for very specific education in fraud investigation and

prosecution and detection for our member companies and individuals. We also serve as a mechanism through which the private payers and law enforcement organizations can and in fact do share information on fraud investigations, indictments, and convictions, and we do so within carefully drawn and appropriate legal guidelines that govern the information sharing we do.

We also serve as a professional network through which the members learn from each other on an ad hoc basis informally and can tap each other's expertise in this area.

Finally, in an area that has been touched on this morning, we strive to keep the public, the media, and Government informed and aware about the nature and the impact that health care fraud has on us all.

The one useful barometer I think, or two, of what is happening generally in health care fraud are two aspects of our operations that tend to mirror the kind of attention the issue is getting. In January 1992, NHCAA had 21 corporate members from the private sector. As of this week we have 43, so we have more than doubled in size as they become more and more aggressive and aware of the need to pursue fraud aggressively.

At the same time, the attendance at our annual education conference where people can learn specific new knowledge about investigation and detection has increased by 30 percent each year in the last 2 years from 290 3 years ago to 550 last year. At the same time NHCAA increasingly is called on by congressional committees, by other Government agencies in an educational and advisory capacity.

As was mentioned earlier, we have participated this year with the Justice Department, the Office of Inspector General, the FBI, and other groups as part of a working group convened first by the Office of Management and Budget last summer, later by the Presidential Transition Office in December to discuss health care fraud and to look at the development of more effective means of dealing with it.

Against that background, I would note, as many others have, that by no means are we talking about a victimless white-collar crime. Beyond the patient care implications that we have heard about from Dr. Marr and others, all of us in the room this morning or this afternoon are its victims, both as people who pay health insurance premiums or copayments and deductibles out of our own pockets on the private side, as businesses, and corporations who purchase health care coverage for their employees. That is a key constituency in this awareness and action process.

Again, we are all victimized twice as taxpayers when Medicare, Medicaid and the other Federal and State government programs are the targets of health care fraud.

As you have heard, it takes a variety of forms, it runs the gamut from individuals providers who routinely and very consciously either fabricate claims in order to receive payments to which they are not entitled or in the same routine conscious manner inflate or misrepresent various aspects of the claim in order to receive a higher benefit or reimbursement than that to which they are entitled; health care supply businesses that telemarket and prey on Medicare and other private programs to ultimately result in billing

for hundreds, thousands of dollars' worth of medical equipment and supplies to people who never knew they were getting them; schemes such as the rolling lab schemes that have been described in good detail this morning to more institutional fraud such as we heard from Ms. Alderson by hospitals, laboratories and clinics, either all or part of whose basic business operation revolves around the systematic commission of fraud.

What the schemes that have been described today have in common is the quite deliberate and criminal intent to commit fraud, and we have attached an appendix to our testimony that delineates a consensus view of the types of activities that by any reasonable judgment constitute outright fraud.

We would agree with everyone who has made the point today that they represent the actions of a very small minority of physicians and any other health care providers, but as we have heard, even a tiny number of people can inflict massive financial damage on the system.

Contrasted to the scope of the rolling labs scheme that was described this morning, at the other end of the spectrum last year one individual physician and his spouse in south Florida were sentenced to prison after having pled guilty to filing more than \$800,000 in fictitious claims over a period of just a couple years. So it ranges from the widespread scheme to the individual committer of the fraud.

The National Health Laboratories case that was reported on earlier, the settlement of \$110 million, represents another type of scheme at work, and we would note about that, that as Mr. Morey said, it is not only the Government who is the target of that kind of scheme. One of the legal documents in that case noted that the company serves approximately 40,000 physicians, so on the private sector they are being heavily targeted as well by these activities.

We have heard various estimates of what we lose. By the most conservative estimate among our members, private and public, the loss to outright fraud amounts to between a minimum of 3 percent to perhaps as much as 10 percent of that national health care expenditure.

The Commerce Department is one of the groups estimating our 1993 expenditure at just under \$940 billion. So by that measuring stick among our members, we are looking at between \$30 billion to perhaps as much as \$94 billion. In terms of what can be done about it or what stands in the way of investigating and detecting and prosecuting more fraud, you have touched on some of the schematic systematic ways in which the system can approach the problem a little better.

I will try to speed my testimony and touch on these points very rapidly for you.

First, the system rests on the presumption of honesty, as does most of our Government and social system. It is geared to paying claims efficiently and rapidly. At the same time that it is being pushed to pay those claims rapidly, often by law, it is being asked to put a stop to all the fraud in the system. That means first identifying a given case as a potential fraud, investigating it with regard for due process, involving law enforcement and prosecutorial authorities on the private side, and finally if it is in court and a

criminal case, proving the criminal intent to defraud, which we have heard is no easy matter.

Identifying the claim at the outset of the fraud is made more difficult by the fact that if it is purely fictitious but conforms to all the required information, there is nothing on the face of it to distinguish it from a legitimate claim. It is only when it does begin to fit into a pattern of activities that is discerned through various means that are applied to that or when it is reported by a beneficiary or an insured person as part of an apparent problem that it begins to come to the surface.

As we have heard, rarely does one provider victimize only Medicare or only one insurance carrier. A key if you are defrauding the system is to spread your activity among a variety of third-party payers so you are less conspicuous with each one of them, and it thus takes longer to detect you among any one of those organizations.

There are a number of obstacles when it comes to investigating and prosecuting the fraud from the private sector standpoint. What is a crime when aimed at the Federal programs, the kickback statutes that have been referenced, is not a crime on the private side. Nor is the systematic waiver of the patient's copayment.

We see it used often as a marketing key device, free services with which to lure patients into these scheme operations, not in a collusive way but as the tools with which the scheme is perpetrated or carried on.

When insurers bring cases for prosecution, they are often confronted with the very real hierarchy of priorities in the prosecutorial office. We have heard today about the increased priority these cases are being given by the Justice Department, the FBI, and those initiatives are very welcome, needless to say.

When insurers investigate cases in good faith and bring them to the authorities, they enjoy widely varying degrees of immunity from civil liability to the targets of those investigations. Some States have strong immunity provisions under which insurers can share information, other States have moderately strong provisions, other States have no such immunity provisions for good-faith investigations whatsoever.

In that context, insurers always have to consider the fact of bringing a case for investigation and prosecution against the reality of probable lawsuits for defamation, slander, malicious prosecution that, even if they are completely without merit, are at best very costly to the insurer, who is representing his customers' interest.

Another reality mentioned today is the uncertainty that even a successful prosecution is going to result in the recovery of the funds lost to the fraud. Those are some of the realities with which the private sector and the Government deal.

We commend the initiatives that this subcommittee is undertaking to identify the ways in which those realities can be altered to let everyone do a better job against the fraud.

I would close by noting two other things that have been cited.

One, the general areas of managed care, "managed competition" and electronic data interchange or electronic processing are viewed widely as areas in which the system might evolve, but as other people have pointed out, neither one of those represents a panacea for

fraud in the system. Almost any system that humans devise will be vulnerable to fraud, and in evolving toward any different type of system we have to keep that in mind and build the safeguards in from the outset.

Again, Mr. Chairman, thank you very much for your attention to the problem, and to your members of the subcommittee.

Mr. SCHUMER. Thank you very much, Mr. Mahon.

[The prepared statement of Mr. Mahon follows:]

**PREPARED STATEMENT OF WILLIAM J. MAHON, EXECUTIVE
DIRECTOR, NATIONAL HEALTH CARE ANTI-FRAUD ASSOCIATION**

Mr. Chairman, Members of the Subcommittee.

My name is Bill Mahon. I am Executive Director of the National Health Care Anti-Fraud Association—NHCAA—which appreciates the opportunity to offer testimony on the nature and impact of what increasingly is acknowledged to be a national crime problem of genuinely alarming proportions.

We commend you, Mr. Chairman, and your fellow members of the Subcommittee for your attention to this problem and your interest in devising means of addressing it more effectively.

Established in 1985 by seven commercial health insurers, one state Blue Shield plan and several individuals from public-sector law enforcement agencies, NHCAA today has evolved into a unique organization that combines the anti-fraud efforts of the private-sector health insurance industry with those of the public-sector administrative and law enforcement agencies responsible for investigating and prosecuting health care fraud. As such, NHCAA is not a trade association, nor is it a lobbying organization. Rather, it is an issue-based cooperative association whose private-sector member organizations account for most of the private health insurance benefits paid in the US, and whose objective is to improve the private and public sectors' ability to detect, investigate, prosecute (both civilly and criminally) and, ultimately, prevent health care fraud.

From the private sector, NHCAA numbers 43 commercial and not-for-profit insurers as Corporate Members; the public-sector members of the Association's Board of Governors are: the Chief of the White-Collar Crime Section of the Federal Bureau of Investigation; the Deputy Inspector General for Investigations

and the Assistant Inspector General for Civil Monetary Penalties of the Office of Inspector General of the Department of Health and Human Services; the Assistant United States Attorney and Chief of the Civil Division for the Eastern Pennsylvania District of the Department of Justice; the Director of the Florida Medicaid Fraud Control Unit; the Medicaid Fraud Counsel of the National Association of Medicaid Fraud Control Units; and, most recently, the Deputy Director of the Office of Medicare Benefits Administration in the Bureau of Program Operations of the Health Care Financing Administration, responsible for monitoring and coordinating HCFA's fraud and abuse detection and deterrence program.

Beyond its Corporate and Public-Sector Board membership, NHCAA also numbers 480 Individual Members, from member and non-member insurers, from self-insured corporations and from a wide variety of other state and federal law enforcement organizations, such as the Defense Criminal Investigative Service, the Office of Personnel Management, the Postal Inspection Service, and state attorneys generals' offices.

NHCAA pursues its overall objective in a variety of very specific ways: (1) by serving as a vehicle for ongoing education in the specifics of health care fraud detection, investigation and prosecution; (2) by serving as a mechanism through which private payors and law enforcement organizations share information on health care frauds (with appropriate legal safeguards); (3) by providing a professional network through which members can learn and benefit from each others' expertise and experience; and (4) by informing the public, the media and government about the nature of the problem and its impact on our society.

The intensity with which attention to health care fraud continues to increase has been manifested dramatically in NHCAA's membership and activities. Between January 1992 and today, for example, the Association's Corporate Membership more than doubled to its present number; and attendance at our annual educational conference has increased by 30% in each of the last two years, most recently to a total of 544 in November 1992.

Paralleling that growth, and highlighting the distinct value of NHCAA's unique private-public makeup, is the continuously increasing frequency with which the Association is called on in an educational and advisory capacity by Congressional committees, state governments and various federal government offices. In recent months, for example, we have worked with the Justice Department, the Office of Inspector General at Health and Human Services, the FBI and other organizations as part of a group convened first by the Office of Management and Budget and again by the Presidential Transition office to discuss health care fraud and the development of more effective means of dealing with it.

Health care fraud is by no means a "victimless" white-collar crime. On the contrary, its victims are all of us here this morning, along with our 250 million fellow citizens who ultimately pay the price for health care in the United States—as individuals who pay health insurance premiums, co-payments and deductibles; as businesses who purchase health coverage for their employees; and as taxpayers (where we are in fact twice victimized) when Medicare, Medicaid and other government payment programs are the targets of fraud.

Health care fraud takes a wide variety of forms. It runs the gamut from individual providers who routinely fabricate or knowingly inflate or otherwise misrepresent claim information in order to receive third-party payments to which they are not entitled—or higher payments than they would otherwise receive; to health care supply businesses that prey on the Medicare program and other payors and attempt to make both physicians and beneficiaries unwitting accomplices in schemes that result in fraudulent billing for millions of dollars worth of medical equipment and supplies; to entities such as "rolling lab" schemes established solely as vehicles for committing fraud within the health care arena; to institutional frauds by hospitals, laboratories and clinics, all or part of whose basic business operation revolves around the systematic commission of fraud.

What these various schemes have in common is the criminal and quite deliberate intention to defraud [see Appendix I, *NHCAA Guidelines to Health Care Fraud*].

As such, we must emphasize our belief that they represent the actions of only a very small proportion of health care providers and others in the field.

Unfortunately, though, given the enormous amount of money at play in our health care system, the actions of even a tiny dishonest minority can inflict massive financial damage on both private and public payors. Last year, for example, an Florida physician and his spouse were sentenced to prison after pleading guilty to having filed more than \$800,000 in false claims with private payors and Medicare. In another recent case, a clinical laboratory firm pled guilty to filing fraudulent claims and will pay the federal government and several state Medicaid programs a total of \$110 million. Meanwhile, the largest alleged scheme identified to date—the California rolling lab case—is alleged to have filed nearly \$1 billion in false claims during the 1980s.

How much do we lose in all? By its nature, the amount lost to any ongoing fraud can never be quantified to the exact dollar and thus must be estimated in an "educated" context. In that context, the members of the NHCAA Board of Governors estimate the loss to outright fraud at between 3% and perhaps as much as 10% of what we spend as a nation on health care each year. In 1993, then, with our total health care expenditure projected to be \$939.9 billion, we estimate a loss to outright fraud of at least \$28 billion—and perhaps as much as \$94 billion. Other estimates place the extent of the loss at even higher totals, but by even the most conservative gauge, it is clear that we are losing many billions of dollars each year.

In this context, we must note that that enormous loss is shared in roughly equal proportions by both the private and public sectors. The Health Care Financing Administration, for example, has indicated that of the nation's total health care bill, 37% is paid by private insurers and 19% by consumers through out-of-pocket payments—for a total of 56%. This private-sector exposure indeed is one rationale for the more aggressive federal initiatives of recent years, and it must be taken into account in the course of creating additional anti-fraud measures.

How are such losses possible?

First, and as a general observation, they stem from the efforts of a small proportion of individuals to defraud a system that, resting on an assumption of honesty, is geared to pay health care claims efficiently and—often by statute—more and more rapidly than ever before. In that context, claims payers find themselves trying to meet demands that at best are not easily reconciled: i.e., to pay claims faster and faster, AND to put a stop to fraud in the system.

Putting a stop to a given fraud means first identifying it as a potential fraud through one or more of the various means employed for that purpose; conducting an investigation with regard for due process; in the private sector, involving law enforcement and prosecutorial authorities; and in the case of criminal prosecutions, proving criminal intent to defraud.

The identification of potential fraud is itself no easy matter, in that a given claim that meets all requirements of form and content—but is purely fictitious—cannot be identified as such on the face of it. Rather, it is when such claims become apparent as part of a given pattern, or when a beneficiary or other individual has called the payor's attention to them suggesting impropriety, that they become suspect.

In addition, rarely does a provider engaged in fraud victimize only one insurer or program. Experience tells us that the same provider who is defrauding Medicare is in all likelihood defrauding the private sector—and vice versa. In that context, a provider will generally spread his or her fraudulent-claims activity among any number of payors—the better to remain inconspicuous and thus prolong the detection process with each.

The investigation and prosecution processes also present the private-sector with a number of obstacles, real and perceived. First, what is a crime when aimed at a federal program is not always illegal when aimed at private payors: the payment of "kickbacks" for referral business that snowballs claims volume; or the systematic waiver of the patient's insurance co-payment, often used as a "free

service" marketing device with which to lure patients into fraudulent-billing schemes.

Second, insurers bringing cases for prosecution often are confronted with the very real hierarchy of prosecutors' priorities, in which health care fraud cases must be weighed according to their nature and financial dimensions. (The Justice Department's more recent initiatives to place a much higher priority on these cases, and its efforts to work much more closely with the private sector on the investigative and prosecutorial levels are extremely well received and will benefit all concerned.)

Third, insurers conducting investigations and bringing cases in good faith do so in an environment of widely varying degrees of potential civil tort liability to the subjects of those investigations. In some states, insurers enjoy relatively strong civil immunity protection in such investigative information-sharing and reporting activity; in others, they enjoy no such protection at all. In that context, they must continually consider the reality of probable lawsuits—at best costly, even if without merit—on such grounds as defamation and/or malicious prosecution in pursuing fraud cases.

Another reality in today's anti-fraud environment is the uncertainty that a successful prosecution will result in recovery or restitution of funds lost to the fraud. The absence of such reasonable assurance represents yet another factor that insurers must weigh in pursuing a given case.

These many realities notwithstanding, the member organizations of NHCAA have long been committed—practically and philosophically—to the aggressive pursuit

of health care anti-fraud activities. Both through our formal activities and via the professional interaction that stems from their membership, those organizations' anti-fraud programs realize a tangible return on their investment in the Association. However, their philosophic readiness to do more will be greatly complemented by the practical provision of more effective tools with which to do so.

In closing, we must look to the future, in which both the broader application of the "managed care" delivery model and all-electronic processing of insurance claims are widely cited as two evolutionary developments that are among the answers to the nation's health care cost and delivery questions. Neither, however, is a panacea for health care fraud—nor is virtually any payment system we might devise. Effective and timely measures against fraud must be incorporated in any evolutionary steps that are taken in order to maximize their benefits.

Again, Mr. Chairman, NHCAA appreciates your attention to health care fraud and looks forward to continuing to contribute to the development of more effective measures to combat the problem.

NHCAA

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GUIDELINES TO HEALTH CARE FRAUD

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Health Care Financing Administration
National Association of Medicaid Fraud Control Units
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Health care fraud is an intentional deception or misrepresentation that the individual or entity makes knowing that the misrepresentation could result in some unauthorized benefit to the individual, or the entity or to some other party.

The most common kind of fraud involves a false statement, misrepresentation or deliberate omission that is critical to the determination of benefits payable. Fraudulent activities are almost invariably criminal, although the specific nature or degree of the criminal acts may vary from state to state.

The variety of fraudulent reimbursement and billing practices in the health care area is potentially infinite. The most common fraudulent acts include, but are not limited to:

1. Billing for services, procedures and/or supplies that were not provided.
2. The intentional misrepresentation of any of the following for purposes of manipulating the benefits payable:
 - a. The nature of services, procedures and/or supplies provided;
 - b. The dates on which the services and/or treatments were rendered;
 - c. The medical record of service and/or treatment provided;
 - d. The condition treated or diagnosis made;
 - e. The charges or reimbursement for services, procedures, and/or supplies provided;
 - f. The identity of the provider or the recipient of services, procedures and/or supplies.
3. The deliberate performance of unwarranted/non-medically necessary services for the purpose of financial gain.

NATIONAL HEALTH CARE ANTI-FRAUD ASSOCIATION

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Mr. SCHUMER. Let me ask both of you from your private sector hats, if you were czar and you could do three things—couldn't change human nature and couldn't change the conditions that create fraud—but you could do three things to reduce fraud and waste and abuse in the system, what would you do that aren't being done now?

Mr. MAHON. I think, Mr. Chairman, I would look at the areas of the law that can alter the realities I have just listed and look at making amendments to the law that would allow the private sector payers to do a more effective job to be more aggressive about investigating and prosecuting the frauds.

Mr. SCHUMER. You think that is the number one barrier?

Mr. MAHON. I think there are some very real barriers there that do constitute a hindrance on the private sector that translates into perhaps less aggressive action than could be taken.

I would also inform and involve the public, the consumers. We have heard how they can be one of the first lines of defense against fraud.

There has been a conventional wisdom that with the exception of Medicare beneficiaries, we tend not to be very good consumers of health care, partly because someone else is paying the majority of the bill on our behalf, but it is up to us to be religious in scrutinizing what is being paid on our behalf and to reporting what appear to be discrepancies there.

Mr. SCHUMER. Ms. Hansen.

Ms. HANSEN. Mr. Chairman, I would answer that by stating, number one, we need tougher law enforcement, and we need to facilitate the ability for insurance companies—

Mr. SCHUMER. Would you mean different laws or more resources? Obviously we need both.

Ms. HANSEN. Right. Because I think that this is something that we are running into, but maybe to be more specific I would say first I would like to see the laws in place that would make it easier for us to actually take that fraud further. In other words, if I want to share information with another carrier or if I want to share it with the local government and the public sector, I feel comfortable doing that. I don't have to worry about—

Mr. SCHUMER. Is it privacy laws or antitrust laws that stop you?

Ms. HANSEN. Privacy laws.

Mr. SCHUMER. Not antitrust laws?

Ms. HANSEN. Right. With that we are facilitating the ability for insurance carriers and the Government to fight fraud together.

Mr. SCHUMER. Couldn't that be avoided by simply deleting the name of a person, inserting instead a number when you shared the information? The name of the person isn't very material.

Ms. HANSEN. I think what was mentioned earlier, and we refer to it as the provider, that we risk civil liability by identifying Dr. Johnson at 1700 Street in Minneapolis, and that is the problem. Then I call up the other carrier and say, "Do you know about this Dr. Johnson."

Mr. SCHUMER. It is not a privacy risk. It is a liability?

Ms. HANSEN. Liability, with confidentiality of that specific provider and blacklisting. And then facilitating the ability for insurers and the Government to work together better, and as I mentioned

earlier, immunity, but the third thing I would add would be mandatory restitution for the private carriers.

We spend a lot of money working on the cases, putting them together. We get law enforcement interested in it, and then zippo, and so it is not very rewarding.

Mr. SCHUMER. I was going to ask you that because it seems to me in a lot of these cases, there is no incentive.

Ms. HANSEN. That is correct.

Mr. SCHUMER. Are you ever able to recoup from previous fraud?

Ms. HANSEN. Yes, we are.

Mr. SCHUMER. Civil suit?

Ms. HANSEN. Either civil suit or if it is a small enough fraud that we put enough pressure on the provider, scare them a little, and he repays us and says, "By the way, would you retract that claim that I submitted to you earlier and send the documents back to me." But actually, you know, our incentive is to catch it up front so that we are not paying anything because of the costs of once we have paid it and getting the money back.

Mr. SCHUMER. That is an interesting answer.

Do you have anything to add, Mr. Mahon?

Mr. MAHON. As you mentioned, stopping the bleeding is a big factor in itself. In the case in Florida I mentioned of the individual physician, he and his spouse were ordered to pay \$565,000 in restitution to private carriers and to government.

So there are cases of money being recovered, but there is in the law no civil cause of action through which insurers can pursue that recovery unless it is awarded in a criminal case.

Mr. SCHUMER. Do you meet regularly with the members of panel II, with Mr. Potts, Mr. Morey, and Ms. Shikles.

Mr. MAHON. We do, Mr. Chairman. Mr. Morey is a member of our board of governors. Tom Kubic, the head of white-collar crime at the FBI, also sits on that board.

Mr. SCHUMER. Do you meet with them? Boards are pretty formal. Do you meet and brainstorm about how to deal with the fraud problem?

Mr. MAHON. We work both formally and informally on the aspects of it.

Mr. SCHUMER. Mr. Ramstad.

Mr. RAMSTAD. Thank you, Mr. Chairman.

Given the hour, I will be very brief. But my main question concerned the interaction that you just described.

I would like to thank both members of the panel for your very enlightening and telling testimony.

I would also call attention to our colleagues who aren't here presently and who will be examining the record, to the four case—studies that you, Ms. Hansen, included, case studies that your company has investigated but which were never prosecuted in a court of law. They are four horror stories of many, many, which I am sure fit this description, but I think as members of this subcommittee and the full committee and indeed everyone in this body needs to look at the legal impediments that are blocking prosecutions, those impediments to prosecutions for cases like the four that you summarized here.

So again, I thank you for your very helpful testimony today.

Ms. HANSEN. Thank you.

Mr. SCHUMER. Thank you.

OK, I want to thank both of our witnesses, and we will be in touch with you as we follow up on this issue.

Before we adjourn, I want to thank my colleagues who participated here. My staff did a great job on this. Dan Cunningham, who was aided by Mark Curtis. And, of course, Andy Fois, the counsel of the subcommittee. I want to thank Lyle Silversmith for being here. And finally, our reporters, who I always try to thank. Today we had Ray Boyum and Ann Blazejewski. I pronounced it correctly, I hope.

Mr. RAMSTAD. A glaring omission, I might add, is not thanking the chairman himself. I applaud his leadership in this important area.

Congress needs to be part of the solution here, and I am hopeful Members on our side working with the chairman and Members on the other side—we need to work together obviously in a bipartisan way to address the problems that have been laid out before us today. We are talking about 10 percent of the gross of the macro—a lot of money spent in this area.

So, Mr. Chairman, I applaud your leadership in this area and in starting the ball rolling here in the subcommittee.

And I would ask unanimous consent finally that my prepared statement be made a part of today's record.

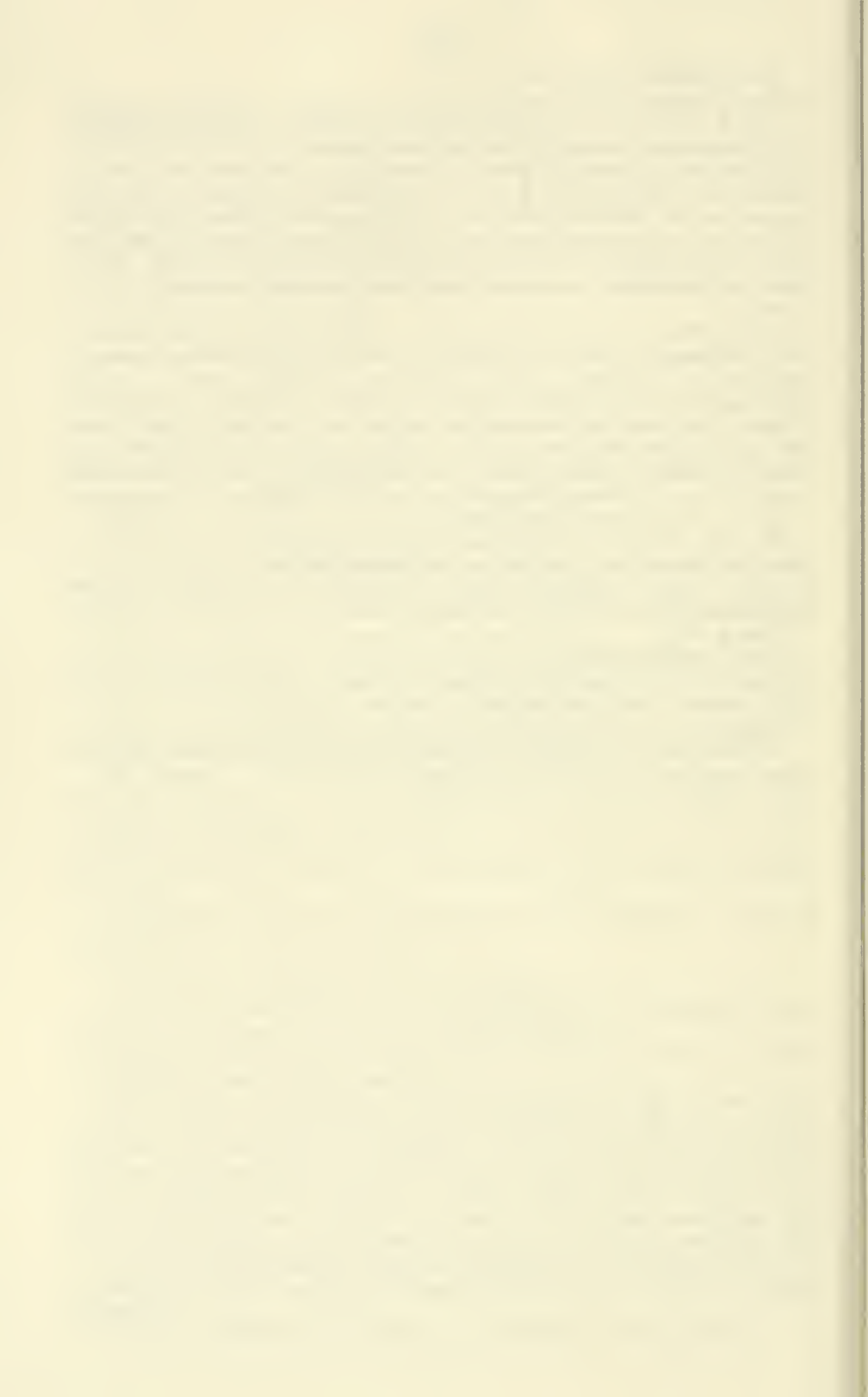
[See p. 92.]

Mr. SCHUMER. Thank you.

And it is Lyle Nirenberg. Lyle Silversmith is the Democratic district leader of the 44th assembly district.

Thank you very much. The hearing is adjourned.

[Whereupon, at 1:05 p.m., the subcommittee adjourned, to reconvene subject to the call of the Chair.]



HEALTH CARE FRAUD

THURSDAY, MAY 27, 1993

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON CRIME AND CRIMINAL JUSTICE,
COMMITTEE ON THE JUDICIARY,
Washington, DC.

The subcommittee met, pursuant to notice, at 11:38 a.m., in room 2226, Rayburn House Office Building, Hon. Charles E. Schumer (chairman of the subcommittee) presiding.

Present: Representatives Charles E. Schumer and John Conyers, Jr.

Also present: Andrew Fois, counsel; Dan Cunningham, assistant counsel; Rachel Jacobson, secretary; Lyle Nirenberg, minority counsel; and Mark Curtis, congressional fellow.

Mr. SCHUMER. The hearing will come to order.

First, the Chair has received a request to cover in whole or in part the hearing by television broadcast, radio broadcast, still photography, or other similar methods. In accordance with committee rule 5 permission, it will be granted unless there is objection.

[No response.]

Mr. SCHUMER. Without objection.

Today, we hold the second in a continuing series of hearings on health care fraud in America, a scourge that bleeds nearly \$80 billion from our health care system annually, and robs our citizens of decent and reliable medical care. AIDS fraud is one of the fastest growing aspects of the health care fraud menace. It preys upon some of the most vulnerable and desperate members of our society. It is a brand of health care fraud that is not only costly to insurers, to government, and to consumers, but it is particularly devastating to immediate victims.

I want to caution everyone here today, AIDS fraud is one of the cruelest faces of health care fraud, and this will be a glimpse into the realm of the truly unscrupulous. This hearing is a warning. The evidence is clear. We are examining a potential epidemic of fraud within an existing epidemic—AIDS.

Consider these facts. According to the Centers for Disease Control and Prevention, one million people in this country are infected with the HIV virus that is associated with AIDS. That is 1 out of every 250 Americans. Many of them don't even know they have it. AIDS is the third leading cause of death among adults age 25 to 44. AIDS cases attributed to heterosexual contact increased by 21 percent in just 1 year. By the end of next year, nearly 500,000 Americans will have been diagnosed with AIDS, and between 320,000 to 385,000 Americans will have died from AIDS.

Like moths to the flame, rip-off artists are drawn to the desperate. This group of ruthless, despicable hucksters and snake oil salesmen prey upon the vulnerabilities of people with AIDS—offering them false hope at a terrible price. And with a pool of potential victims that is expanding exponentially, AIDS fraud unfortunately promises to be a growth industry.

One-by-one, consumer protection agencies and law enforcement officials are reporting more and more AIDS fraud cases all over the country. Not just in places like New York and Los Angeles, but in cities like Indianapolis and Chandler, AZ. In the early years, an AIDS diagnosis was a near certain and swift death sentence. Although there is still no cure, treatment such as the drug AZT and the combination therapies are now available that can delay the onset of symptoms in persons infected with HIV. Such treatments can also dramatically improve the quality of life for those who develop full-blown AIDS.

But, for those who it does not claim immediately, AIDS can have a debilitating effect on the quality of life, slowly sapping strength and vitality and robbing many of its victims of a livelihood and the ability to participate in the most basic activities of daily life. In spite of the newly available treatments, the death toll from AIDS rises grimly upward.

As it is quite understandable, many people with AIDS are willing to try almost anything in a dire attempt to beat this disease. And imagine what a desperate parent, a child, a spouse or a friend wouldn't do, what expense they wouldn't spare to save a loved one from the tentacles of AIDS. If you can imagine that, it is no surprise that AIDS cure scams have become one of the fastest growing brands of health care fraud in America.

Today we will hear from several victims of AIDS fraud. What was done to them is ugly. It is unsettling. But we need to hear it, for these victims and the scams in which they were trapped are just the tip of the iceberg in a growing national disgrace.

No one can look at these cases and not feel a sense of outrage. The criminals who prey upon the despair of these vulnerable people rip-off our health care system, rob their victims of what little money that have left, and hasten death—all in the name of making a fast buck.

Not all unapproved AIDS treatments constitute AIDS fraud, and I want to underline that. No interest is served by unnecessarily denying patients access to drugs or treatments that may hold some promise against the scourge of AIDS. Those treatments deserve to be moved through the certification process with all dispatch that is prudently and legally allowed.

I believe the FDA is doing its best in this respect. However, when treatments are offered as part of a scheme designed to "make a fast buck," providing no tangible medical benefit knowing that the alleged medicine doesn't work, that is fraud. It is criminal, and it should be stopped.

While the impact of AIDS fraud upon its immediate victims is sickening, the cost of AIDS fraud are borne by all of us. AIDS fraud crooks target PWA's, people with AIDS, who have insurance, billing the insurance company for the bogus treatment by disguising it as a legitimate treatment on claims forms. This raises costs to insur-

ers, and sends the premiums of all consumers higher. Government programs designed to assist indigent PWA's are bilked. Most regrettably, when PWA's are harmed by bogus treatments, or convinced to stop taking legitimate therapies, their conditions often deteriorate rapidly, increasing health care costs for critical care and unnecessarily abbreviating their productive lifespan.

It is time to target AIDS fraud as part of our assault on health care fraud in America. It is time for us to face the crisis in health care fraud, streamline prosecutions, unleash our law enforcement officials, and hunt down the health care crooks who stalk our citizens.

I plan to introduce legislation to address each of these goals, targeting health care fraud on all fronts, including AIDS fraud. One provision of that bill will enact a new health care fraud felony that will put health care crooks behind bars for up to 5 years. It will include aggravated offenses. Health care fraud, including AIDS fraud that causes serious injury, will cost the guilty up to 25 years in prison.

I have discussed this proposal with the First Lady, and have sent it to her, and we are working with the White House so that we can introduce this legislation concurrently when the health care fraud package is announced.

Tough penalties and tough enforcement, however, are only part of the solution to this crisis. Health care fraud crooks thrive on the ignorance and isolation of their victim. The most potent weapon we have against them is an informed consumer. Our Federal health agencies must aggressively inform the public that these charlatans are out there, and they must be wary. Nowhere is this more important than in AIDS fraud.

I applaud the FDA's current efforts in this area, particularly its support of the AIDS fraud task forces in various regions of the country, but our efforts to inform the public must be bolder. I urge the FDA and HHS to be more aggressive in not only investigating AIDS fraud but also in publicizing the various AIDS scams as widely as possible. It is an important message and the lives and well-being of a significant number of our citizens may depend upon it.

As part of that effort, this hearing must send a clear and unequivocal message: if you steal the dying days from a person with AIDS, you will spend costly years in a Federal prison. Only stiff penalties, tough enforcement, and most important, public awareness will cure the opportunistic infection of AIDS fraud, and today's hearing is an important step toward eradicating that national disgrace.

I thank the gentleman from Michigan for his indulgence, and would you like to say a few opening words?

Mr. CONYERS. If it could only be kept to a few, sir, I would be very honored to make a couple of comments.

First of all, I congratulate you and agree with you.

Second of all, I would like to just add another dimension for our consideration since we haven't talked about it directly. Overt fraud is obviously detestable. I am against fraud to AIDS victims just as much as I am against fraud to any other kind of victim, to be quite honest with you. A person with cancer that's being defrauded is in

no better or worse predicament than anybody else. But this is particularly heinous and very offensive because we are in an epidemic of international proportions for which there is a great deal of medical debate going on about how we proceed.

That leads me to my point, which is that we need to examine malevolent doctors and clinicians and people not even in the health field posing as experts. But I would like to review our National Institutes of Health and our Communicable Disease Centers in Atlanta to examine theories and practices that are borderline. This we can't get outraged on because where the line of science and where the line of misperception and improper activity begin is a very thin line. For us, it may be one at one place and for others in the medical community it might be another.

But I will tell you, Mr. Chairman, what brought this to mind. I was in Gabon only yesterday in which the African-American Summit called by Rev. Leon Sullivan was being put together. I flew over with Dr. Lewis Sullivan, our former head of HHS, and Reverend Jackson and Joe Lowery and Andy Young and Rev. Jesse Jackson and Dorothy Height. So you get the flavor. Plus 15 heads of state of the African country.

But there were, I was surprised to find, a number of African-American doctors present, and one began talking to me about, did I know about this great controversy raging about some AIDS solution, a medical solution. I can report this to the committee because I didn't know anything about it. She said it was highly controversial.

The thing that left me impressed enough to relate it to you and recall it was that she never told me what side she was on and it was like this is another interesting government medical battle of which some are on this side and some are on that side. I noticed her position was—and maybe I shouldn't ask people in a mere social accidental conversation in the lobby of a hotel, but that she should send me a summary of her prepared remarks, but I did notice that she was very careful not to identify where she came out on this, and that raises this gray area where it is not people with criminal intent, but there are people promoting things that they know damned well won't work.

Now, whether that's a medical crime or should be in the statutes I am perfectly unprepared to pass judgment, but it seems to me that that gray area should encompass the concern and the jurisdiction of your subcommittee, and it is that area that I am very, very interested in.

The other area that interests me greatly is the consequences of AIDS on the African-American population in the United States of America who are being singularly bypassed in this whole effort and concern, singularly bypassed, and to talk about what the effect of this disease and its consequences are on the continent of Africa are too numbing to even recall. I am not in a position to do that, and I will keep the records open to make certain that that is established and that I am not overreacting or being rhetorical.

But out of that neglect comes a predisposition to go for anything: around-the-corner remedies; back-alley gossip, what I heard somebody said worked that cured over in Africa; in this particular country, they have developed a cure for AIDS and we can't get it into

the United States because you know they won't give us credit for anything, and so we have to surreptitiously bring it in anyway. I think that these considerations fall amply within the scope of your jurisdiction and I am looking forward to the witnesses that you have assembled here this morning.

Mr. SCHUMER. Well, I thank you, Mr. Conyers. Certainly, the areas you bring up are both very important and really merit discussion. The line you talk about is obviously one that we will have to explore in terms of determining what is fraudulent and what is not.

There are obviously some people who believe there are certain cures that really do work. They may not work, they may not be licensed, but that is quite different than a quack who comes along and just dupes people, the people we will hear about.

Just to open the hearing, it would be worth seeing a brief little film clip. The people to go after—the quacks, the crooks who go after people with AIDS—can be very convincing, and they are also great capitalists. They send around these video marketing tools and ask you to play it and you will see. Just imagine yourself either being a person with AIDS, or having a loved one who is, and getting one of these tapes. This man is a pure quack. Look at what he says and how convincing it is, and imagine your own reaction if you got this tape and you knew you might be dying.

The tape goes on for 20 minutes. No, this is not an issue of debate, it has no medical abilities to cure. In fact, we will hear from Randy Payne on our first witness panel of his experiences with ozone, but you get that tape, this man appears to be a physician, we don't know if he is, and appears to offer a lot of reassuring hope. With that, let me call our first panel to come to the witness table.

The first panel is Mr. Looney, Mr. Henke, Mr. Payne, and Mr. Koontz.

It's Looney, Henke, Payne, Koontz, from my left to right from your right to left, gentlemen.

Our first panel is composed of three victims of AIDS fraud—different kinds of AIDS fraud—as well as an attorney who is representing 10 AIDS patients who were harmed by phony AIDS treatment.

Mr. James Looney of Los Angeles learned in 1989 that he had the AIDS virus. When a key measure of his immune system began to drop, Mr. Looney began using an underground treatment known as Viroxan which was touted as an AIDS cure. Mr. Looney will tell us of the horrible medical side effects he suffered from Viroxan, side effects which carried a \$20,000 price tag.

Mr. Randy Payne of Indianapolis learned that he had the AIDS virus in 1992. He learned of an underground treatment involving ozone therapy at a clinic in Monterrey, Mexico. After enduring more than 2 weeks of intensely painful ozone and homeopathic treatments, he escaped from the clinic and later cooperated with the New York City Department of Consumer Affairs in its efforts to prosecute the clinic's operators.

Mr. Thomas Koontz, who has been HIV-positive for more than a decade, is currently the executive director of the Manhattan Center for Living. His organization serves over 3,000 people with AIDS in

the New York City area and is the support of more than 800 volunteers. He was targeted by the same scam that victimized Mr. Payne.

With Mr. Looney is his attorney, Mr. Raymond Henke. He's a senior partner in the law firm of Henke & Associates and he specializes in AIDS fraud, drug product liability, and medical malpractice. Currently, he's the lead counsel in the Viroxan case, one of the Nation's most important AIDS fraud cases.

I want to thank all of you for coming to testify today. We've received your prepared statements and without objection they'll be read in the record. We'll begin with Mr. Looney, then we'll hear from Henke, Payne, and Koontz.

Mr. Looney, you may begin.

STATEMENT OF JAMES LOONEY, LOS ANGELES, CA

Mr. LOONEY. May it please the chairman and honorable Members of the U.S. House of Representatives, Committee on the Judiciary's Subcommittee on Crime and Criminal Justice.

Shortly after being diagnosed HIV-positive, I presented to a physician who told me the truth about my disease, a truth I found unsatisfactory. It is a terminal illness for which medicine does not have a definitive cure. As anyone would, when confronted with a serious illness, I sought a second opinion from a physician with a large HIV/AIDS practice.

Mr. SCHUMER. Mr. Looney, could you just move the microphone a little closer to you. You can move it right in front of you and lift it up. It has that flexible arm. Thank you.

Mr. LOONEY. Valentine Birds, M.D., was, for all appearances, a very respectable physician who talked knowledgeably, or so it appeared, about drugs and remedies he claimed would cure the disease or raise the T-4 helper cell levels to a point at which I could look forward to a normal life and a normal life expectancy.

One aspect of his credibility which impressed me most was his association with an apparently respectable AMI Hospital which seemed to be actively involved in cooperating with the testing of this drug. For example, Dr. Birds would have monthly meetings at the AMI Hospital attended by 50 to 60 patients each month in which Dr. Birds would discuss his modalities of treatment and indoctrinate patients into his philosophy of medicine. Later, the AMI Hospital agreed to discount the surgical fees in connection with the insertion of the Hickman catheter, an indwelling plastic tube into my superior vena cava at the entrance of my heart for infusion of the drug Viroxan.

I learned about Viroxan when the principal investigator, Stephen Herman, M.D., made a presentation at one of the Valentine Birds' monthly meetings. Herman discussed the experience of other HIV and AIDS patients who had said they had spectacular results on the drug, their T-4 cells elevating substantially, the primary index of immune health.

I was provided promotional material with the graphs and charts demonstrating that Viroxan would elevate these indices of immune health and cure the symptoms of AIDS and prevent opportunistic infections. Most importantly I was told that in addition to these physicians that the AMI Hospital was involved in this alleged

"phase I clinical trial." It had agreed to discount its hospital fees to induce the Viroxan patients to take part in the experiment and to be catheterized for the infusion of the drug. A document entitled, "Approximate Cost for Hickman Catheter Insertion" discussed that the hospital had cut its costs as low as possible to make this modality for infusion of Viroxan affordable.

Based upon the endorsement of the hospital and the recommendations of Drs. Herman and Birds, I had the Hickman catheter placed at the hospital. Once the Viroxan extravasated from the catheter into the tissues of my chest. Also, the Viroxan mummified the tissues of my hip. The experimenters did no preclinical testing for safety. It scares me how callously they took risks with my life inducing me to pour quantities of this caustic material into my heart through delicate valve that they could not have known would survive the substance any better than the mummified muscle tissue.

I believe that my life has been foreshortened by the fact that while on these fraudulent treatments I was led to forgo legitimate efficacious modalities of treatment which prolong life. Others of the Viroxan patients died, some horrible deaths, their bodies racked by septicemia. One was Mark Snyder who was found lying in a bathtub where he had lain for 3 days before being found by his landlady who called Dr. Birds, only to be told that it would be "all right." Shortly thereafter, he was dead, and the autopsy demonstrated the rampant systemic infection. Some of my colleagues in this litigation, one woman a cancer patient, who was treated with Viroxan became horribly septicemic and had to be hospitalized a number of times and is now disabled. Another after having the catheter inserted was so fearful about the device he pleaded with Dr. Birds and the AMI Hospital surgeon to remove this indwelling catheter. The response of the doctors was to ask how he intended to pay for the removal. His insurance had just expired. He waited for an appointment at a public hospital, but first developed a systemic infection which led him to be hospitalized in convulsion and nearly dead. Others developed PCP pneumonia by reason of the failure of these physicians to prophylax or diagnose or treat the disease. Many have gone on to develop opportunistic diseases. These are my colleagues in this test litigation which we all hope will send a message by the example we hope to make of this AIDS fraud and the physicians and hospital who so cynically exploited us. To deter health fraud is the purpose of our test litigation.

The Viroxan scandal is not past tense. Stephen Herman, now operates his international AIDS fraud scheme from his new location in Florida, selling the drug, manufactured now at the Kenya Medical Research Institute through the Bahamas and Tijuana. My attorney has discovered contracts between Herman and KEMRI providing for the commercial exploitation of African AIDS patients. My attorney and the epidemiologist who headed up the Centers for Disease Control AIDS Fraud Task Force jointly wrote the Centers for Disease Control AIDS Fraud Task Force Global Program on AIDS, World Health Organization, Geneva, Switzerland, providing the documentation of the local scandal and the international conspiracy to exploit Third World countries with this horrible product. The Chairman of the organization, Global Program, in turn advised

the Kenyan Foreign Ministry, however, it is our information that the use of Viroxan in African patients continues.

We are all very encouraged that we are no longer alone in this battle. The subcommittee on Crime and Criminal Justice and in particular the chairman are to be congratulated for their sensitivity in recognizing this plague of health fraud upon us and for seeking to fashion a solution.

Mr. SCHUMER. Thank you, Mr. Looney.

[The prepared statement of Mr. Looney follows:]

PREPARED STATEMENT OF JAMES LOONEY, LOS ANGELES, CA

May it please the Chairman and honorable members of the United States House of Representatives Committee on the Judiciary's Subcommittee on Crime and Criminal Justice.

Shortly after being diagnosed HIV positive, I presented to a physician who told me the truth about my disease, a truth I found unsatisfactory. It is a terminal illness for which medicine does not have a definitive cure. As anyone would, when confronted with a serious illness, I sought a second opinion from a physician with a large HIV/AIDS practice. Valentine Birds, M.D. was, for all appearances, a very respectable physician who talked knowledgeably, or so it appeared, about drugs and remedies he claimed would cure the disease or raise the T-4 helper cell levels to a point at which I could look forward to a normal life and a normal life expectancy.

One aspect his credibility which impressed me most was his association with an apparently respectable AMI hospital which seemed to be actively involved in cooperating with the testing of this drug. For example, Dr. Birds would have monthly meetings at the AMI hospital attended by fifty to sixty patients each month in which Birds would discuss his modalities of treatment and indoctrinate patients into his philosophy of medicine. Later, the AMI hospital agreed to discount the surgical fees in connection with the insertion of the Hickman catheter, an indwelling plastic tube into my superior vena cava at the entrance of my heart for infusion of the drug "Viroxan."

I learned about Viroxan when the "principal investigator" Stephen Herman, M.D. made a presentation at one of Valentine Birds monthly meetings. Herman described the mechanism by which the drug was intended to work, mimicking the respiratory burst phenomenon by which lymphocytes kill viruses with superoxide. Herman described the University of California, Irvine animal studies he said demonstrated the drug's safety. Herman discussed the experience of other HIV and AIDS patients who he said had spectacular results on the drug, their T-4 cells elevating substantially, the primary indicity of immune health.

I was provided promotional material with the graphs and charts demonstrating that Viroxan would elevate these indices of immune health and cure the symptoms of AIDS and prevent opportunistic disease. Specific patients were described as having been ill with neurological and other symptoms who after taking Viroxan returned to normal immune indices and enjoyed a clearing of all symptoms. Most importantly, I was told that in addition to these physicians that the AMI hospital was involved in this alleged "phase one clinical trial" and it had agreed to discount its hospital fees to induce the Viroxan patients to take part in the experiment and to

be catheterized for the infusion of the drug. A document entitled "Approximate Cost for Hickman Catheter insertion" discussed that the hospital had cut its costs as low as possible to make this modality for infusion of Viroxan affordable.

Based upon the endorsement of the AMI hospital and the recommendations of both doctors Herman and Birds, I had the Hickman catheter placed at the hospital. It was a plastic tube that emanated from my chest. It went into my superior vena cava, that primary vein leading directly into the right upper chamber of my heart. The tube was placed, in essence, into the entrance to my heart. Every day I would hang a saline bottle, warm the Viroxan by rubbing it with my hands and then inject it into the indwelling catheter. Once the Viroxan extravasated from the catheter into the tissues of my chest. My entire upper torso blew up for months, I now know that the Viroxan mummified the tissues of my hip, and I also know that these experimenters did no preclinical testing for safety. It scares me how callously they took risks with my life inducing me to pour quantities of this caustic material into my heart through delicate valves that they could not have known would survive this substance any better than the mummified muscle tissue. Both doctors led me to forgo the efficacious treatments for HIV disease. Both doctors referred to AZT as "poison." Valentine Birds told me that if I took AZT that I would be dead within six months and two years.

On Birds instructions I was injected twice per week for several months with typhoid vaccine on the theory that AIDS was tertiary syphilis and that the vaccine would cure HIV by bringing the syphilis out so it could be treated. The informational material provided to me on the typhoid vaccine protocol was very specific, in its admonition that AZT was contra-indicated.

I believe that my life has been foreshortened by the fact that while on these fraudulent treatments I was led to forego the legitimate efficacious modalities of treatment which prolong life. Others of the Viroxan patients died, some horrible deaths, their bodies racked by septicemia. One was Mark Snyder who was found lying in a bath tub where he had lain for three days before being found by his land-lady who called Dr. Birds, only to be told that he would be "all right." Shortly thereafter, he was dead, and the autopsy demonstrated the rampant systemic infection. Some of my colleagues in this litigation, one woman cancer patient who was treated with Viroxan became horribly septicemic and had to be hospitalized a number of times and is now disabled. Another, after having the catheter inserted, was so fearful about the device he pleaded with Dr. Birds and the AMI hospital surgeon to remove this indwelling catheter which he found so intolerable. The response of the doctors was to ask how he intended to pay for the removal of his catheter. His insurance had just expired. He waited for an appointment at a public hospital, but first developed a systemic infection which led him to be hospitalized on an emergent basis in

convulsions and nearly dead. Others developed pneumocystic carinii pneumonia by reason of the failure of these physicians to prophylax or diagnose or treat the disease. Many have gone on to develop opportunistic diseases. And while these may in a sense be the destiny of the AIDS patient, it is my sense that by reason of their more thoroughly depleted immune systems they became susceptible much earlier in their disease than they otherwise would have if they had been treated timely and appropriately. These are my colleagues in this test litigation which we all hope will send a message by the example we hope to make of this AIDS fraud and the physicians and hospital who so cynically exploited us. To deter health fraud, is the purpose of our test litigation in the same sense that the purpose which I understand these hearings will concern to make AIDS fraud a crime also with the object to deter this plague of health fraud practice which is so epidemic of some sectors of the medical and institutional response to our own epidemic of HIV disease.

The Viroxan scandal is not past tense. Stephen Herman, having relinquished his medical license to the California Medical Board, now operates his international AIDS fraud scheme from his new location in Florida, selling the drug, manufactured now at the Kenya Medical Research Institute through the Bahamas and Tijuana. My attorney has discovered contracts between Herman and KEMRI providing for the "commercial exploitation" of African AIDS patients. My attorney and the epidemiologist who headed up the Centers for Disease control AIDS fraud task force jointly wrote to Global Program on AIDS, World Health Organization, Geneva Switzerland providing the documentation of the local scandal and the international conspiracy to exploit third world countries with this horrible product. The chairman of the organization, Global Program, in turn advised the Kenyan Foreign Ministry however it is our information that the use of Viroxan in African patients continues.

We are all very encouraged that we are no longer alone on this battle. The Congress of the United States, the Judiciary Committee, The Subcommittee on Crime and Criminal Justice and in particular the Chairman, the honorable Charles S. Schumer of New York are to be congratulated for their sensitivity in recognizing this plague of health fraud upon us, and for seeking to fashion a solution.

Mr. SCHUMER. Mr. Henke.

STATEMENT OF RAYMOND L. HENKE, ESQ., HENKE & ASSOCIATES, WEST HOLLYWOOD, CA

Mr. HENKE. Thank you very much. May it please the honorable House Judiciary Committee, Subcommittee on Crime and the honorable chairman and members of the subcommittee. My name is Ray Henke and I represent Mr. Looney and nine other AIDS patients and, in fact, one cancer patient in the litigation involving Stephen Herman, the manufacturer of Viroxan.

What I would like to do at the outset is to change a little bit from what I intended to do and that is to respond to some of the questions that were raised by Mr. Conyers.

First of all, we also felt that while the primary point that we wanted to make was that AIDS fraud was epidemic and needed to be stopped that it was not the only problem and health fraud is a problem generally for persons suffering from terminal illness. So as one of the test clients, I represent a cancer patient who was treated by the same doctors, the same way, and it is characteristic of the snake oil that it is touted as a cure for whatever ails you. That it is a product that, as we saw in the film, that may be proposed as being useful for a lot of maladies. In this case for cancer, for AIDS, for acne, for sunburn, for bee stings, for insect bites, for venereal warts, this product was patented for snake oil.

The second question that Mr. Conyers raised was the question of whether there might be cures coming out of African countries that we should attend to and I think that we should be open, certainly, to everything that is potentially useful. I want to address the flip side of that which is one that causes me an actual recurrent nightmare and that is that Viroxan—this ozone therapy in this case—ozonated terpene which is without any question without merit. After having been brought to task by the California Medical Board and the criminal authorities in California the developer has moved his operation to Florida where he has entered into contracts with an African investigator and research institutes in Kenya where they have, according to their contract, set out to commercially exploit the African AIDS patient. And my recurrent nightmare is the line along a dirt road leading into the Kenya Medical Research Institute with men and women and children with AIDS who have sold their family's wealth in cattle to gain the few shillings to buy a bottle like this of Viroxan, a bottle that will not serve them, only deny them the wealth of their family built on generations.

The issues that I would also like to raise today, and perhaps if I don't finish them in my testimony the Congressmen will ask me: First of all, to comment further on the schemes that were involved in this case, second, to describe the purpose of our litigation to deter AIDS fraud by punitive damages, third, to described this one product liability lawyers' and trial lawyers' ideas on what might be a useful and provable legislative object.

First of all, to comment further on the schemes that were involved in this case. The manufacturer was Stephen Herman. He was a retired radiologist. I asked him in deposition what his credentials were to develop a drug for AIDS and he indicated to me that he had 1,000 credentials. I asked him in deposition to name

40. He said he couldn't. I asked him to name 10. He said he couldn't. And I asked him to name one, and he said he couldn't. And he couldn't because he didn't have any credentials.

He came up with a superficially plausible pseudoscientific explanation for why his product should be useful in the treatment of AIDS. He then proceeded to develop an imaginary data base that he would use to convince AIDS patients that the product was useful.

He first injected them intermuscularly with the drug which killed whatever tissue it came in contact with and left golfball size lumps of dead meat on their body, found to be mummified tissue. He then needed, because this was very painful, to find another modality for infusion of the drug and he centered on the concept of the Hickman catheterization, which is the placing of the tube essentially into the entrance of the heart.

He brought this to a hospital which had been actively involved in health fraud for the past few years previous to that with the second character in this, who is a what we would call, a quack and by virtue of that relationship had this done at the hospital with the cooperation of the hospital, which again led patients to believe this was credible. In fact, the catheterizations were done to great detriment.

Let me just make one more point in response to Mr. Conyers' question whether physicians with knowledge that a product is ineffective should fall into the category of health fraud. They do under FDA regulations. It's considered health fraud and the reason for that is that it leads people who are suffering from diseases that require efficacious treatment to forgo efficacious treatment to their detriment and really it is equally as criminal as to use drugs that directly damage them.

Thank you.

Mr. SCHUMER. Thank you, Mr. Henke.

[The prepared statement of Mr. Henke follows:]

PREPARED STATEMENT OF RAYMOND L. HENKE, ESQ., HENKE &
ASSOCIATES, WEST HOLLYWOOD, CA

The General Accounting Office has found that ten percent of all the wealth of this nation spent on health care is paid to purveyors of health fraud, 80 billion dollars annually.

The schemes take the form of health fraud, the use of false treatments and fraudulent remedies often on desperate and vulnerable patients suffering terminal illness; and health care fraud, the submission of false claims to health insurers and other collateral sources including governmental entities.

Two classic health fraud schemes are commonly described in medical terminology, FDA policy guidelines, and folklore as "quackery" and "snake oil" sales. In a test case in California, two physicians who exemplify everything that is characteristic of these classic health fraud schemes are being prosecuted by my clients, ten representatives victims of the fraud. They are AIDS patients and one cancer patient, all seriously harmed by reason of the fraudulent treatment and lack of appropriate treatment for their serious medical conditions.

The effect of health fraud upon this new and growing class of particularly desperate and vulnerable health care consumer, and the effect of the fraud upon the medical support systems which have and will need to continue to be properly funded by whatever national or other health care system the United States Government, in its humanity, shall fund, is most profound in the toll of health care fraud upon the patients' physical well being.

This toll may be direct injury by harmful side effects and complications, or the toll may be the indirect effect of non-efficacious treatment to the exclusion of standard efficacious treatment which might have avoided complications or prevented opportunistic disease. Each results in increased cost of medical care associated with the treatment of more advanced disease or complications associated with the treatment itself.

Health fraud, when billed either to the medical consumer or to the consumer's medical insurance provider or other collateral source is a cost which must be borne as a dollar ill spent as our economy must adjust to responsibilities for health care generally and for that growing number of us who are stricken each day by HIV disease.

In addition to the dollars spent on fraudulent cures and remedies, physicians, hospitals and other health care providers participate in a practice of false billing of insurance companies and other collateral sources, which also places unworthy demands upon our health delivery systems.

The test litigation which the undersigned is prosecuting involves the first California civil case, and the first or one of the first nationwide by AIDS patients against their medical providers for fraudulent procedures and remedies misrepresented as cures for HIV and AIDS. The defendants are first, a sophisticated modern day snake oil salesman, Stephen Herman, M.D., a retired radiologist who conceived a superficially plausible but in fact unequivocally false and meaningless theory

for a "drug" which he said would mimic the T-4 cells method of killing viruses by spewing superoxide he claimed he could create by splurging ozone through any of a variety of base chemicals. Herman, as the snake oil salesman of old, first sought to patent this mixture as a cure for sunburn, venereal warts, chicken pox, arthritis, vaginal infections, herpes lesions, acne, insect bites, bee stings and as a contraceptive device. Herman later tried to sell it as disinfectant soap the Japanese and conceived to market it as an antidote to chemical warfare to the U.S. Government. From the beginning, his scheme, as he confided to his colleagues, was to become wealthy from the sale of this patent.

Herman attempted to sell the rights to the drug to a variety of drug companies, including Abbott Laboratories, which tested the drug and wrote back that its scientists had determined that the drug was "inactive against bacteria, fungi, and viruses, including HIV." Herman by that time had already bilked one wealthy investor for hundreds of thousands of dollars. He was undaunted by this evidence that his product was inert.

There was one type of data, however, which a potential pharmaceutical manufacturer could not disconfirm and that was human data. Human data could not ethically be disconfirmed, at least short of FDA approved clinical testing following the very expensive preclinical testing required for approval of an Investigational New Drug Application. And no drug company would be likely to expend that type of resource without first

purchasing Herman's patent rights.

Herman began using the drug on AIDS patients without any of the preclinical evidence of safety or efficacy which would have been required by FDA prerequisite to human investigation. By the end of 1989 Herman had experimented on hundreds of AIDS patients by his own account. While he certainly took a substantial amount of money from the AIDS patients, \$300 each for a month's supply of the drug "Viroxan," it is clear that Herman's primary object was to exploit the AIDS patients for selected of their immune panels for use in bilking investors in the drug.

The primary index of immune health is the number of T-4 cells per cubic centimeter of blood. HIV disease is a terminal illness by reason of the consequent reduction of T-4 helper cells which leave AIDS patients susceptible to the opportunistic diseases to which they commonly succumb. People infected with HIV do not, however, take a gradual steady decline. Rather, the T-4 levels in every patient, including the untreated patient, will go up for months and then down, up and down, the cumulative valleys over time deeper than the peaks, ultimately leading to severe immune deficiency, opportunistic disease and death.

Out of the hundreds of AIDS patients Herman injected with this ozonated chemical, he "selected" five or ten whose T-4 levels by random variation one would expect in a population of untreated patients so large to go up during any arbitrary study period. Just as Herman would show these few selected immune panels to prospective experimental subjects, he provided the same

data to potential financiers and investors.

Just as with the snake oil salesman of old, Herman had a "charismatic" capacity to persuade according to one investor whom Herman bilked for \$200,000. Similar statements were made by another investor whom Herman convinced to give him hundreds of thousands of dollars. And he used the same "evidence" to persuade these intelligent mostly educated but certainly desperate and vulnerable AIDS patients that he had the "cure" for this troublesome virus that had heretofore so stumped all of the most brilliant and appropriately educated scientists working around the clock in every part of this world with every motivation including the Nobel Prize.

Herman himself had to acknowledge upon interrogation that he knew nothing of scientific methodology, the purpose for a protocol, written methodology, appropriate controls, avoidance of confounding variable, or the statistical analysis necessary to divine meaning from raw data. Herman's lack of any appropriate scientific training assured that the human waste he would wreck by his experiments would yield no information useful to science or to the cause of persons with AIDS. However, that was clearly not his object.

At first Herman injected his subjects intramuscularly, which was extraordinarily painful since the mixture of chemicals "mummified" the tissue into which it was invested leaving permanent lumps of dead muscle, each the size of a golf ball following an injection, some patients building plateaus of dead

meat on their hips, others dropping out by reason of the extreme pain.

Herman needed a hospital and a surgeon to join in the experiment, to surgically implant indwelling plastic catheters into the superior vena cava, the primary vein leading directly into the right upper chamber of his subjects' hearts. By that time all that was known about this drug was that it caused the death of muscle tissue. No mode of administration studies had been conducted in animals. And yet Herman conceived to infuse this caustic chemical with the consistency of refrigerated honey, almost certainly unsterile, directly into the chambers of the right heart through delicate heart valves and into the blood streams of the severely immune deficient patients. Herman contacted none of the hospitals at which he had previously worked. Herman found the AMI-Medical Center of North Hollywood (henceforth AMI Hospital), a hundred miles away, and its staff physician, Valentine Birds, M.D., whose quackery and idle human medical experimentation were both well known in the community and to the AMI Hospital which had not only tolerated but encouraged him in his scientific and medically egregious idle human medical experimentation for years.

Valentine Birds, M.D. was the quintessential "quack" as that term has been used in the FDA policy guidelines pertaining to health fraud, as the term is used in the medical profession, and as the term was used most commonly by the nurses of the AMI Hospital, as an adjective to describe Birds' practice, and as a

noun to describe the physician to all of his patients admitted to the Immune Suppressed Unit.

AMI Hospital had invited Birds to join the medical staff and provided him an office suite in the desirable hospital office building despite that it was informed that he had previously had his medical license revoked by the California Medical Board (revocation stayed, licensed suspended, followed by probation). Birds, explained the Chief Administrator, had a large practice. His patients would be likely to "utilize" the hospital facilities. The hospital made a business decision.

The hospital was well aware, as testified the Administrative Medical Director of the Immune Suppressed Unit, that Birds' care was "below standard," "detrimental," and "dangerous." The staff and administration of the AMI Hospital were well aware that Valentine Birds used upon his substantial population of AIDS patients none of the standard medical treatment, never an antiviral or prophylaxis or standard treatment for opportunistic disease. Birds told his patients the standard modalities were "poison" and would kill them. And every level of employee, staff and hospital administration has acknowledged in testimony a full awareness at all times that Birds was involved exclusively in the most flagrant of quackery and the most egregious of idle human medical experimentation.

AMI Hospital was aware that Valentine Birds did not treat any of his patients with AZT or prophylaxis for *Pneumocystis carinii* pneumonia according to the standard of care. AMI was

fully aware that Birds rather treated his patients with a host incontestably quack remedies. As was acknowledged by the Administrative Medical Director of the AIDS Ward and the nurses each admitted complaining repeatedly through administrative channels to the Chief Administrator of Birds' use of typhoid vaccine which was not a part of the medical repertoire of any other physician in Los Angeles, actually detrimental to the immune system, having the additional characteristic of causing symptoms, including fever which would mask the onset of severe of and deadly opportunistic diseases.

The hospital staff and administration was further aware that Dr. Birds was treating his AIDS patients with homeopathy, his reasoning being that the atomic imprint on the essentially pure dilutant which comprise homeopathic drugs would "resonate" with the patient's "life force." Birds used a black box called a "Voll" machine with dials and gauges and two wires which he would attach to the patient's index fingers "to create a circuit", twisting the dials to ascertain the patient's imaginary "organ frequencies" and "toxin frequencies."

As the nurses of AMI Hospital testified, Birds used the black box also to "cure" anal and genital herpes by attaching the same electrodes to the affected areas and twisting the same dials that were used to discern "toxin frequencies." In fact, the hospital permitted Dr. Birds to order the physical therapy department to use a similar box on hospitalized herpes patients. Perhaps most tragically, the hospital was fully aware that Birds

was treating his pneumocystis patients with Vitamin C to the exclusion of the proper antibiotic modalities.

Pneumocystis carinii pneumonia is a most deadly opportunistic disease, the primary killer of AIDS patients prior to the advent of the current antibiotic treatments. Birds uniformly refused to treat his patients with these standard proven effective modalities in favor of intravenous Vitamin C. This was not only dangerous but idle human medical experimentation. Patients would arrive at the hospital with advanced pneumocystis carinii pneumonia totally emaciated from months of untreated diarrhea associated with cytomegalovirus with their arms, according to the nurses, so "fried" from the intravenous Vitamin C that they could not find a vein to initiate the appropriate modalities to try to save their lives.

The nurses were the only heroes at the AMI Hospital. They commonly risked losing their jobs by telling Dr. Birds' patients admitted to the hospital that he was a quack, that his treatments were detrimental and dangerous and to seek any other physician. One nurse described in testimony that she told all of Birds' patients. The nurses testified that they conveyed up every staff and administrative channel known to them their concerns that Dr. Birds was not practicing conventional medicine and that his unconventional medicine was detrimental and dangerous. They testified they complained to the administrative medical director who in turn testified that he brought both his concerns and the nurses' concerns to the Chief Administrator of AMI Hospital. The

response was to stifle the complaints, to tell the nurses that this is not their place. The administrative nurse manager to whom the nurses also vehemently complained of the quackery, of the idle human medical experimentation and of their unwillingness to participate in it took the concerns to the Vice President of Nursing Affairs and to the Chief Administrator, and the response was unequivocal: Birds may order any drug including Vitamin C for any disease. It is not for the nurses to question him. If he orders it, hang it. And under no circumstance tell Birds' patients the treatments are unconventional and do not ever suggest that they seek other physicians.

According to the former Chief Administrator of Cedars Sinai Medical Center, a 1,100 bed non profit hospital in Los Angeles with an international reputation, in testimony before the court:

"I am professionally appalled by the actions of the defendants in this case, which might have been expected to have been tolerated not later than the 1920's, prior to the 1938 Amendments to the Food, Drug & Cosmetic Act, long prior to the adoption of the Joint Commission on Accreditation of Hospital Standards, where patients were at the mercy of patent medicines, the snake oil salesman who peddled them, and hospitals which had no choice but to accept a standard of practice which was characterized by quackery and health fraud."

It was his testimony, furthermore, that the AMI Hospital

should have revoked Dr. Birds' staff privileges as soon as it became aware of the character of his practice, his use of homeopathy, typhoid vaccine in the treatment of his AIDS patients and certainly upon discovery of his most egregious experimentation with Vitamin C for the treatment of pneumocystis. According to the Joint Commission on Accreditation of Hospitals, a hospital has an obligation for the quality of patient care and for the competency of its staff physicians. In this obligation clearly the AMI Hospital failed when it continued to tolerate and then went on to endorse and ultimately promote this staff physician's fraud.

Knowing all that it did of Valentine Birds, AMI, instead of revoking his staff privileges, offered him large meeting rooms to solicit and indoctrinate patients in his quackery. The hospital provided the "forum" for Birds' "Open Forum Discussions" to which 40 to 60 AIDS patients would descend upon the AMI Hospital each month to hear Birds talk about the efficacy of his black box to cure herpes, his theory that AIDS is actually syphilis, Birds' rational why typhoid vaccine was a "cure" for AIDS, and how homeopathic remedies resonate with the "life force."

It was at an "Open Forum Discussion" that Dr. Birds introduced Dr. Herman to several of the AIDS patients on whose behalf this test litigation has been brought. Herman described the superficially plausible but scientifically meaningless mechanism Viroxan's purported efficacy. He passed around the selected immune panels. And he presented a couple of healthy

looking HIV patients who claimed to have been brought back from the brink of death by Dr. Herman.

In Valentine Birds, Herman not only found the means to expand his subject population, he found a cooperative hospital staff physician and access to a hospital which would not only tolerate, but actively endorse and participate in this utterly illegal human medical experimentation. After all, it was business as usual for Dr. Birds and this AMI Hospital. The hospital did not require institutional review of this experimental protocol any more than it had with any of Birds previous idle human medical experiments. In fact, it entered into an agreement with Birds to discount its hospital fees to cash paying experimental subjects who would agree to undergo the Hickman catheter procedure for infusion of Viroxan. And the hospital offered to all insured Viroxan subjects that if they would be catheterized for infusion of the drug, it would accept in payment for its hospital services whatever their insurance would pay and would not seek to recover from the patient the excess of their bill above the insurance payment.

The hospital's endorsement of the Viroxan experiment yielded a bonanza of subjects for Dr. Herman and an epidemic of catheter surgeries for the hospital, more in one day than by all physicians at this hospital in the three months previous. And the assembly line surgeries went on for more than a month.

Just as Valentine Birds in his practice was accustomed to billing his quackery to health insurance providers as treatments

for disease entities unrelated to any disease suffered by the patient, diseases which were, however, reimbursable by the insurance company, AMI Hospital, also well aware that these were HIV and AIDS patients being catheterized for infusion of an unapproved drug, billed the hospital charges for the Hickman catheter surgeries to insurance companies as indicated for chemotherapy treatments for "lymphoma." It was only in the records to be provided to the insurance company that lymphoma was stated as the diagnosis. In the operating logs, the diagnosis was stated as HIV. And in the billing records, 75% of which have been "lost" by the hospital (despite an admitted one percent or less record loss rate), the in-house billing department records would state HIV, and for the same patient the same AMI Hospital billing department would bill the patient's insurance companies under a diagnosis of "lymphoma."

The Chief Financial Officer of AMI Hospital was deposed in June of 1992 and asked to state whether the hospital following the Medical Board findings of fraud had considered reimbursing the insurance providers who had been improperly charged for their fraudulent treatments, to which inquiry the hospital attorneys objected, permitting the witness only to acknowledge that he was unaware of any such discussion.

The health care fraud as described in the insurance billings of Valentine Birds and the AMI Hospital are undeniable examples of the type of health care fraud which contributes substantially to the statistics provided by the General Accounting Office. It

is unfortunately true that especially for patients suffering from terminal disease, most commonly AIDS and cancer patients, health fraud of the types exemplified by Drs. Herman and Birds are tragic not only for the economic effects which are substantial, but perhaps more poignantly in its human toll.

Helen Mac Eachron, one of the ten test cases, suffering from Hodgkin's disease, was induced by Herman, Birds and the AMI Hospital's endorsement to participate in the Viroxan experiments and to infuse the drug by Hickman catheter. She was the first of the patients to have this plastic tube implanted for infusion of the drug. She started infusing Viroxan with all the hope inspired by promises of a non-toxic cure for her cancer. Within days she was back at the AMI Hospital with a rampant blood infection which ultimately required multiple hospitalizations and left her disabled, the infection having entered her hip. The cost to the health care system was not only surgical and hospital fees improperly billed to an insurance company, but the cost of the series of hospitalizations which followed and the ongoing care and potential future costs of hip replacement. Parenthetically, following Miss Maceachron's septicemia, Birds, Herman and AMI continued the assembly line surgeries without regard to the likelihood that the drug was adulterated and unsterile.

Roderick Garcia, an AIDS patient, was induced by the representations of Drs. Birds and Herman and AMI Hospital's endorsement and offer of discounted hospital charges to submit to

the implantation of the same central line for infusion of the caustic ozonide. Mr. Garcia's insurance company, however, balked at the submission of charges following implant of the catheter. Mr. Garcia wanted the catheter out almost as soon as it was put in. He found it extremely painful, uncomfortable and worrisome. He pleaded with his physicians to remove the catheter. Dr. Birds asked him how he intended to pay to have the catheter explanted. The surgeon responded similarly. Mr. Garcia waited for an appointment with the county hospital until he had to be carried in, shaking with convulsions from the septicemia, his physicians acknowledging that had he waited any longer, he would not have survived. Mr. Garcia was so traumatized by this experience that he has never seen a physician since, and he has remained untreated from that day until this. Mr. Garcia is impecunious and therefore the expense of the superior medical care he received at the County hospital, which certainly saved his life, presumably has been borne by the state.

Timothy Johnson infused Viroxan by catheter for eight months and then by intramuscular injection for an additional seven months thereafter. Midway through his treatment, he developed flu-like symptoms. Herman's "Viroxan Patient Instruction Sheet" listed a number of symptoms which the sheet urged Viroxan patients to ignore, as positive signs that the immune system was "healing." Unfortunately, the symptoms listed were also the presenting symptoms of pneumocystis carinii pneumonia. Notwithstanding Dr. Herman admonition to ignore the symptoms,

however, Mr. Johnson presented to Dr. Birds who also assured him that all was well. Unprophylaxed for pneumocystis carinii pneumonia on Birds' instructions, unbeknownst to Mr. Johnson, he was suffering from this deadly disease, and by reason of the delay in treatment would require hospitalization by another physician at a different hospital to resolve the opportunistic infection. Mr. Johnson also developed deadly cryptococcal meningitis while on Viroxan and off of AZT on Birds' and Herman's instructions. Since discontinuing Viroxan and initiating conventional modalities, he has since remained free of new opportunistic diseases. The costs associated with the hospitalizations for the pneumocystis carinii pneumonia and cryptococcal meningitis, as well as the ongoing care for the latter, has been borne by private insurance, the premiums are satisfied by a humanitarian program funded by the State of California.

James Looney was inspired by the results Herman touted of early Viroxan success, including that of James Templeton. Mr. Templeton had had lower T-4 results but his had risen to the same level of Mr. Looney, at the time approximately 400. Mr. Templeton treated with Herman thereafter continuously from 1989 to the fall of 1992 when my associate, C. Sterling Wolfe, took Mr. Templeton's deposition on his death bed in Abilene, Texas. A true believer in Dr. Herman, Mr. Templeton continued to receive his Viroxan supply in the mail, wrapped in brown paper package without a return address. Mr. Templeton testified that Dr.

Herman continued to monitor him and his Viroxan treatments by telephone. Within two months of his deposition, Mr. Templeton was dead.

As a result of Drs. Birds' and Herman's joint disparagement of AZT, Mr. Looney forewent the drug until the middle of 1991. Since then he has initiated AZT and combination AZT/ddI therapies. Between that time and this, his T-4 levels have risen almost to normal. The relative results of Mr. Looney and Mr. Templeton are anecdotal. In and of themselves they prove nothing about the relative efficacy of these two modalities. The results, however, are typical on the one hand of the extensive epidemiology on the efficacy of AZT to cause an initial rise in T-4 levels followed by a more gradual decline over time resulting in extended life and extended disease free life. The result of Mr. Templeton is also typical of the experience of all of the AIDS patients in my probably representative subject population in that the immune panels on each of the test plaintiffs went down on Viroxan without exception, not up as all of Herman's selected promotional data had indicated. The experience of Mr. Templeton and the AIDS patients participating in this test litigation while they were on Viroxan are essentially the experience one would expect of HIV infected patients left untreated by reason of health care fraud. The experiences of these men and woman, the opportunistic diseases, the hospitalizations, the human suffering and the cost to the health care system are the human toll and economic toll of health fraud.

Pharmaceutical consumer protection legislation is provided in a number of federal statutes and I can comment upon the State of California statutory scheme by way of example. The United States Food, Drug & Cosmetic Act is the primary source of federal pharmaceutical consumer protection legislation. It is found at 21 USC Section 301, et seq. and sets forth the prohibited acts at Section 331, law pertaining to adulterated drugs at Section 351, law pertaining to misbranded drugs at Section 352 and the New Drug Regulations at Section 355. The latter scheme prohibits introduction into interstate commerce of any new drug unless FDA has approved a New Drug Application, Section 355(a) and (b) or approved an Investigational New Drug Application, Section 355(i).

By way of example, the State of California Pharmaceutical Consumer Protection Scheme, the California Sherman Food, Drug & Cosmetic Law, Health & Safety Code Section 26000, et seq. incorporates the federal statutory scheme, extending the reach to activities which do not occur in interstate commerce. Similar law is provided pertaining to adulterated drugs, Section 26610, et seq., misbranded drugs, Section 26630, et seq.; and its own new drug regulations requiring an FDA approved, New Drug Application, Section 26670; or an FDA approved Investigational New Drug Application, Section 26678.

Health & Safety Code §26679, provides the State of California the authority to approve New Drug Applications for potential AIDS drugs, another avenue for AIDS patients to receive access to legitimate AIDS drugs under appropriate regulation.

And Health & Safety Code §26679.5 provides for approval of legitimate AIDS drug trials by qualified physicians and scientists under the review of an AIDS vaccine department advisory committee. Specifically to avoid the economic factors which certainly drove the illegal experimentation herein, the statute provides that: "No person may contract with department for the review of a request under this subdivision if the person has a financial interest or conflict of interest involving the drug being evaluated." Of further interest, California Health & Safety Code §26463 makes it "unlawful" for any person to advertise any drug or device to have any effect in any of the following conditions, disorders or diseases: ... Acquired Immune Deficiency Syndrome (AIDS); AIDS related complex (ARC); and diseases, disorders or conditions of the immune system.

Since many of the AIDS fraud schemes are fashioned as "human experimentation" or in fact constitute human experimentation, another applicable body of law is the law pertaining to Protection of Human Subjects in Medical Experimentation. International human rights law is binding only to the extent that it is codified. However, the issue is governed morally by the Nuremberg Code of Ethics in Human Medical Research and the Helsinki Declaration. On the federal level, there is law pertaining to the "Protection of Human Subjects in Biomedical and Behavioral Research". See 47 Federal Register No. 60, p. 13272; also "Protection of Human Subjects: Informed Consent." 46 Federal Register, No. 17, p.8942; and "Protection of Human

Subjects" 45 CFR, Section 46.100.

The State of California also has a Protection of Human Subjects in Medical Experimentation Act, Health & Safety Code Section 24170, et seq., including the California "Human Subjects Federal Rights," Sections 24172-3. The statutes specifically intended to codify the Nuremberg Code of Ethics in Human Medical Research. See Preamble to Health & Safety Code Section 24171.

Notwithstanding all the law, and notwithstanding the epidemic proliferation of AIDS fraud which has responded to the desperation and vulnerability of this new and fast growing population of medical care consumer, there has been only one criminal prosecution for AIDS fraud in California, that being the prosecution of Dr. Herman. And there has been only a single Medical Board prosecution of an AIDS fraud doctor in California, that being the prosecution of Drs. Birds and Herman. Dr. Birds proceeded to trial and his license was revoked for the second and hopefully the last time. Dr. Herman relinquished his license to the California Medical Board in exchange for their not revoking it. He pleaded his felony criminal case to a misdemeanor, paid a small fine and has moved to Florida, where he is certainly eligible and would have no difficulty in obtaining a medical license if he should so choose, by virtue of his deal with the California Medical Board.

During the Medical Board and criminal prosecutions, Herman submitted an amateurish "pre-IND" to FDA to which the Agency responded immediately with a thoughtful statement of position

finding that Herman's proffered "pre-clinical" data were meaningless, and that the proffered selected human data were meaningless, admonishing Herman that his human experimentation "was a most serious violation of the U.S. Food & Drug Act." The FDA warned Herman to cease and desist using Viroxan or any other unapproved drug on human patients within the jurisdiction of the United States. So now in Florida Herman distributes his drug out of the Bahamas and Tijuana, Mexico. And in perhaps the saddest chapter of this scenario, having been kicked out of California and told by the FDA to cease his operation nationwide, Herman has entered into a contract with an internationally debunked Kenyan scientist by the name of Davy Koech, Ph.D., who several years ago claimed he could turn HIV positive patients HIV negative in another story of international AIDS fraud. Now Dr. Herman and this Kenyan scientist have contracted to "commercially exploit" the African and other third world AIDS patients with Viroxan.

The undersigned and Donald Francis, Ph.D., former head of the Centers for Disease Control, AIDS Task Force and AIDS Laboratory, an epidemiologist who on loan from CDC to the World Health Organization was pivotal in the elimination of Small Pox from the Sudan and Ebola Fever elsewhere in Africa, have together written to the Chairman of Global Programme on AIDS, World Health Organization in Geneva, pending the documentation I was able to obtain from Dr. Herman including this commercial contract with the Kenyan scientist who would be doing the human studies in Africa explicitly to help their commercial promotion of the drug,

just as Herman did here. I was informed by the Chairman of Global Programe that he has in turn contacted the Ministry of Health in Kenya to inform them of the scientific improprieties documented in the contracts. It is hoped that in this manner another international health fraud scandal can be averted. It is from this Kenyan manufacturing facility, however, that Herman obtains the Viroxan he continues to ship back into the United States through distributors in the Bahamas and Tijuana, Mexico.

The California Medical Board, notwithstanding the good people including Kathleen Schmidt who initially investigated the case, and the district attorney's office which prosecuted the criminal matter, in my opinion, and I believe also in Ms. Schmidt's opinion, failed both to adequately punish these most reprehensible crimes, and failed altogether to set an example of the health fraud which might otherwise have deterred others from committing similar offenses. Ms. Schmidt has acknowledged that she felt Herman should have been prosecuted for manslaughter, and I would only add, or worse. In my opinion, furthermore, Herman should not have been allowed to relinquish his medical license, the license should have been revoked. Accepting the relinquishing of Herman's medical license only solves California's problem with the physician. He and others like him are free to seek their licensure in any other state without the hindrance of prior license revocation to explain.

The message to AIDS fraud physicians in California was, "ply your trade with impunity." The odds of being prosecuted are

virtually nil. And if you are prosecuted, you may buy your peace with a small fine and a free trip to wherever else AIDS patients can be found in sufficient numbers to make the trade in fraud worthwhile.

The purpose of this test case, in addition to compensating the victims of this fraud for their suffering and medical expense, is to obtain exemplary damages to set an example of Herman, Birds and the AMI Hospital, for the health care community to consider. The hope of my clients and myself is that other AIDS fraud doctors and hospitals that would collect ill gotten dollars at the expense of these desperately ill patients, will see that the dollars may be taken away from them and then some, in civil punitive damage judgments which are neither insurable nor dischargeable in bankruptcy.

I applaud the work of this Committee and the Honorable Chairman for considering this issue. I agree wholeheartedly with the concept that legislation is needed which will fairly and clearly distinguish criminal health fraud from responsible science and proper health care, setting forth clear criteria which comport with due process and yet provide the prosecutors effective means to prove the elements of the crime. For those who are proven to have participated in health care fraud, particularly upon the desperate and vulnerable terminally ill, and in the process have injured them either directly, or, indirectly by depriving them of the appropriate and proven efficacious standard modalities of treatment, I further agree

that substantial prison sentences are not only appropriate punishment but will provide the deterrent to health care fraud which under the present scheme is lacking.

This Honorable Subcommittee should consider hearing from the Food & Drug Administration and the best in AIDS and cancer science and medicine. It is my observation that these leaders in AIDS and cancer research will be willing to participate in formulating legislation that reduces the incidence of AIDS and cancer fraud so that the product of their hard work, the fine advances that they have made, won't be for naught because a quack or snake oil salesman has convinced the patient to forego the good that true science has and will yield. Volunteering to testify in this test litigation in California is Professor Luc Montagnier, the virologist who discovered HIV, Michael Gottlieb, M.D., the physician who discovered AIDS, Don Francis, Ph.D., the CDC epidemiologist who headed up the AIDS Task Force in the early 1980's, Marcus Conant, M.D., who led the battle against AIDS on both the medical and political front in San Francisco, Roger Detels, Ph.D., the principal investigator on the longest running and largest epidemiologic cohort observing homosexual AIDS patients, Alan Done, M.D., a former special assistant to the Director of Drugs, Food and Drug Administration, William Pryor, M.D., a preeminent chemist, recipient of an NIH merit grant, and especially Dr. Peter Wolfe, who when he is not sitting on national scientific advisory committees, has made a special study of health fraud and has provided his kind assistance in educating

me on the nuances of scientific principle and method which distinguish science from quackery.

This Honorable Subcommittee should also consider hearing from the legitimate AIDS and cancer patient advocacy groups, perhaps most prominent here in California, Project Inform, headed by Martin Delaney. I suspect that the development of appropriate criteria to permit the legitimate science, even that "pushing the envelope," while at the same time prohibiting the cynical fraud exemplified in the activities of Drs. Herman and Birds and the AMI Hospital, will not be simple. Whatever criteria for the crime are ultimately legislated, however, the crime should be prosecuted without exceptions so that the agency charged with enforcing the law will not be seen as turning its back on some violations as has occurred in the enforcement of the Federal Food & Drug Law which makes outlaws of some who probably should not be so stigmatized for their idealism, while the practice permits others less idealistic to ply their trade within a loophole.

If in the process, in the interest of those presently dying, a compromise will need to be made, in the track to an investigational new drug application, this is better than having studies run outside of the supervision of government which might vary, as they have in the past, from on the one hand such well controlled studies as operated by Project Inform, to, on the other hand, this methodless and cynical operation conducted by Dr. Herman. It is my lay opinion that the Food & Drug Administration has made appropriate compromises. There is an

extraordinary body of experience embodied in ingenious rules and regulations built up over the course of more than half a decade from the 1938 amendments to the Food Drug & Cosmetic Act, pharmaceutical consumer legislation which required for the first time that drugs be proven safe, through the 1962 amendments, responding to the Thalidomide tragedy, after which new drug manufacturers were then required to prove both safety and efficacy.

The criteria set forth in the U.S. Food, Drug & Cosmetic Act and the regulations promulgated thereunder as respects the procedures for obtaining an Investigational New Drug Application, in my opinion, which would likely be different from some equally well informed AIDS advocates is that they are generally appropriate, and any major overhaul in the name of streamlining access to investigational drugs would be detrimental to the object of protecting the pharmaceutical consumer including those suffering from AIDS. Literally hundreds of drugs have created enormous excitement since the time AZT first came on the market in the mid 1980s. Thousands of patients were exploited in scams similar to those of Herman, Birds and the AMI Hospital, others misled unfortunately by well meaning physicians and scientists, all led to forego efficacious modalities of treatment, and almost always for naught. Only two of the antiviral drugs have ultimately been demonstrated safe and efficacious, sufficient for NDA approval, ddI and ddC, and most physicians would agree that AZT is still the antiviral of choice.

Adequate preclinical testing to assure the safety of new pharmaceuticals, in the undersigned's opinion, should never be compromised. Unfortunately, while many of the best AIDS advocacy groups insist on the unfettered right of choice, most AIDS patients while often intelligent and educated such as the ten I represent, first are at the mercy of what the drug promoters tell them, in this case that the Viroxan study was a phase one clinical trial under the auspices of NIH, and second, often reasonably, they may also consider the credentials of those involved. In this case, Valentine Birds had one of the largest AIDS practices in the San Fernando Valley. Stephen Herman was a medical doctor and seemed to know what he was talking about. And the experiment was endorsed by an apparently legitimate hospital. While the AIDS patient may be intelligent, educated, and sophisticated, he is also desperate and he is vulnerable to those who would tell him that he need not die.

FDA has made some reasoned efforts to adjust to the AIDS epidemic. However, the agency has also been pressured improperly into making clearly bad decisions. For example, the granting an investigational new drug application to Low Dose Oral Alpha Interferon, an essentially homeopathic remedy, a capitulation to pressure which almost all scientists across the nation would agree and those at FDA would surely privately concede was a bad judgment. The manufacturer of the drug is the same Kenyan scientist who is now manufacturing Viroxan and distributing it in Tijuana. As a result of the decision to permit the IND, the

patients who receive this ill-conceived homeopathic remedy first touted by the Kenyan scientist as capable of turning patients from HIV positive to HIV negative, with the Government's endorsement will for no good reason suffer diminished immunity and foreshortened life expectancy because for the period of the study they will remain untreated. FDA must be permitted to operate without undue political pressure. To the extent that compromises are made in the rigorous requirements that a drug be proved safe and efficacious, the consequences will be realized in the damage and detriment to the AIDS patients and will ultimately be borne by society.

In addition to making whatever changes are necessary to insure that the food and drug law can be strictly enforced without exception, a law dealing specifically with health fraud and health care fraud with a clear definition and substantial penalties is clearly needed.

Finally, and importantly, given the economic forces which will likely govern the number of investigators who can be made available to investigate and prosecute health care fraud, and I am informed that there are only three such investigators currently assigned to all of Southern California, this Clinton Democrat would suggest to the Democratic Congress a page from the economic lessons of Presidents Ronald Reagan and George Bush that the legislation encourage or at least that it refrain from discouraging the involvement of the private sector in the accomplishment of the public goal.

Medical malpractice and drug product liability attorneys have in many respects done as much for the safety of drugs and as much for the quality of the medicine we enjoy today as the FDA and state boards of medical quality assurance. This is true not only for medicine and drugs, but for the cars we drive, the toys our children play with, and the non-flammable blankets we tuck our children into at night. It was the FDA's Francis Kelsey who is credited with preventing an American Thalidomide tragedy in 1961. At the same time, trial attorneys have identified the dangers of scores of dangerous drug products from the Dalcon Shield IUD to the most recent association of silicon breast implants with auto-immune disease, hidden from the public view by a failure of the medical device industry to conduct appropriate epidemiologic follow-up. And the truth is that it has been in large part medical malpractice and product liability litigation which has kept the medical and pharmaceutical industries as honest as they are.

Punitive damages are the most important remedy to fraud, because they are not insurable and are nondischargeable in bankruptcy. Usually, to succeed the plaintiff must prove malice, oppression or fraud. In California, the plaintiff must also demonstrate that the conduct was despicable, and against a health care provider the plaintiff must also establish in a pre-trial motion that he has a substantial probability of establishing at trial clear and convincing evidence of "despicable" malice, oppression or fraud.

Punitive damages constantly come under attack by medical associations and manufacturing groups who suggest that they should not be punished for their despicable malice and fraud. I suggest that punitive damages actions in the state courts should be seen as a friendly adjunct to the federal scheme in the fight against health care fraud. We are private attorneys general. We accomplish the same purpose to deter the fraudulent physician who would prey on the desperate and vulnerable to their detriment and who would by their health fraud create the unnecessary costs within the health care system. We private attorneys general, however, do not charge the Government for our work. We serve our clients in the private sector and are paid by our clients.

The final recommendation that I would make is that the drafters consider providing for a civil cause of action permitting exemplary damages or other remedies to civil litigants prosecuting litigation under the statute. However, in any litigation drafted, please remember the following words from the Hippocratic Oath, which the AIDS fraud doctors clearly forgot along the way: "First do no harm." Write the legislation which at least does not preempt state remedies including punitive damages available to civil litigants against health care fraud practitioners. If between us, the public sector and the private sector, we are able to reduce the prevalence of health fraud, it seems that many of President Clinton's aspirations, and those of our Democratic and Republican Congressmen and woman for universal access to health care will be as much as ten percent more

economical to achieve, and as important, the most desperate and vulnerable among us, those most deserving of our solicitude, may be provided a safer medical environment free from cynical fraud and quackery.

I applaud the Honorable Representative from Brooklyn New York, the Chairman of this sub-committee and the other Honorable committee members for considering this complex and most important subject. I applaud both your good sense for recognizing the economics of health care fraud and your humanity for attempting to ameliorate this epidemic of AIDS health fraud and the human damage it wrecks in its path.

SUMMARY OF ARGUMENT

Health fraud is a serious American medical and economic problem. For the country it means billions of dollars each year in lost wealth at a time when each dollar spent for health care should be used efficiently and to good effect. There is also the victim's tragedy, exploited by sharp medical practitioners, often at the expense of his health in addition to his pocket book. Perhaps those most susceptible to health fraud are the terminally ill, mainly cancer and AIDS patients. Their desperation and vulnerability are exploited by often sophisticated practitioners and purveyors of snake oil and quackery.

Boards of Medical Quality Assurance and state prosecutors are often ineffective in controlling what has become an epidemic of AIDS fraud as the medical practitioners, and hospitals and other health care providers vie for the wealth of this new epidemic of desperate and vulnerable pharmaceutical and medical health care consumers.

I have brought a civil action by ten patients against and extraordinarily sophisticated snake oil salesman who claimed to have the cure for AIDS, a quack who treated his AIDS patients with typhoid vaccine on the theory that AIDS was tertiary syphilis, homeopathy, and Vitamin C for such opportunistic diseases as pneumocystis carinii pneumonia. The medical care was selected by a black box with dials and wires which supposedly diagnosed the patients "organ frequencies" and "toxin frequencies." The hospital joined in all of the health fraud stifling all complaints by its nursing and medical staff, cooperating in the promotion of the quackery, providing meeting rooms for the solicitation and indoctrination of new patients and offering discount surgery to induce patients to have indwelling plastic tubes implanted into the entrance of their hearts for infusion of a drug which was known only to destroy muscle tissue upon IM injections. Patients became septicemic, and some died. All suffered diminished life expectancy. From the French virologist who discovered HIV to the American physician who discovered AIDS, to the epidemiologist who headed up CDC's AIDS Fraud Task Force and twenty others of the most eminent physicians in the world, have agreed to testify for the plaintiffs in this case. Testifying against the hospital is the former Chief Administrator of Cedars Sinai Medical Center, an internationally recognized medical institution in Los Angeles.

It is an object of the litigation not only to compensate the plaintiffs for their injuries but also to obtain punitive damages to set an example of the health fraud for medical practitioners who would similarly exploit the terminally ill to consider. It is the object of exemplary damages to deter wrongful conduct which the undersigned sees as a friendly adjunct to the work of the Subcommittee.

We applaud the Chairman and United States House of Representatives Judiciary Committee, Subcommittee on Crime and Criminal Justice for considering this issue so important to the lives and health of so many.

Mr. SCHUMER. Mr. Payne.

STATEMENT OF RANDY PAYNE, INDIANAPOLIS, IN

Mr. PAYNE. Good day, gentlemen. My name is Randy Payne and I am from the Midwestern United States and am a PWA.

Prior to the time that I went on medical leave I served as an underwriting department employee for a major health insurance company. During the summer of 1992 I learned from my physician that I am HIV-positive. I became a PWA in October of the same year.

During the course of my conventional treatment I followed my doctor's advice but also became interested in alternative therapy for the treatment of my condition. A friend put me in touch with a man by the name of Ed McCabe, who publishes Oxygen Therapies. McCabe believes that PWA's can benefit from the use of ozone. He claims that the introduction of ozone into the human body will kill the AIDS virus.

In early November 1992, I called Mr. McCabe and asked him about ozone. McCabe put me in touch with Mr. Carl Vollmer of Brooklyn, NY. On or about November 10, 1992, I spoke by telephone with Vollmer. He told me that he had a clinic opening in Monterrey, Mexico, that would use ozone for the treatment of HIV-positive individuals. Mr. Vollmer further represented the following: (1) that the treatments had successfully converted patients from HIV-positive to HIV-negative states; (2) that after 30 days of these treatment that he would, quote, "promise but not guarantee" that I would be HIV-negative, and (3) that when I came back from my successful treatment in Mexico that I would be guaranteed a six-figure income working for him as a spokesman for his cure for AIDS.

You see, although I did not fully realize it at the time, Vollmer viewed me as a "cash cow." He knew that I had worked for a health insurance company and he saw me as a chance to get inside an insurer, convince the company that the treatment that he offered was legitimate, and get the company to pay for others to take the treatment.

On or about November 15, 1992, at my own expense, I flew down to Monterrey, Mexico, to enter the clinic owned by Mr. Vollmer. The clinic was located in a lower class residential section of Monterrey, Mexico. The clinic itself consisted of a converted duplex on which the construction had not been completed. The heat was sweltering. It was a very unpleasant environment.

Upon the evening of my arrival I met with the clinic's doctor, Peter Rothschild. Dr. Rothschild instructed me to stop taking the medications that my physician had prescribed including AZT. After my arrival, I discovered that the clinic's professional medical staff was not strictly made up of professionals. For example, Dr. Rothschild's brother-in-law, Juan, was supposedly a registered nurse. Juan later admitted to me that he was an unemployed construction worker and had had no formal training at all.

During my stay, there were three other patients undergoing the clinic's ozone therapy treatment, two women from New York City and one man from Los Angeles. The man from Los Angeles was in a very poor state of health and expired while undergoing treatment there in Mexico.

The course of treatment outlined by Dr. Rothschild included the following: (1) all patients undergo indepth physical and laboratory examinations upon arrival. This turned out to be a joke in that I was taken to a local barber shop where blood tests were drawn by a technician that used whiskey as an antiseptic before and after blood draws; (2) during the first 15 days of treatment, the patient was to be nourished only with fruit and vegetable juices; (3) ozone therapy is administered twice daily, both by rectal insufflations and by intramuscular injections; (4) low pressure colon therapy was to have been administered to all patients, but the machine was broken down; and (5) homeopathic injections of various substances were to be given daily.

For the benefit of the subcommittee, I believe it is important for me to describe in some detail two aspects of the treatment that I received, ozone therapy and homeopathic injections.

Gentlemen, I apologize in advance to anyone who might be offended by my description but it is important for you to hear the facts.

The ozone treatments consisted of rectal insufflations and intramuscular injections. The rectal insufflations were accomplished twice daily by having an enema nozzle connected to clear plastic tubing, which in turn was connected to the ozone generator. The ozone was fed rectally until the patient could hold no more. This form of treatment was excruciating, producing almost unbearable stomach cramps along with severe inflammation to the anus.

The intramuscular injections were accomplished by feeding the ozone from the generator through plastic tubing into syringes. The syringes were then placed into the tricep area of the arm and slowly discharged into the muscle tissue. Due to the volume of ozone injected, the area would swell under the skin to about the size of a golfball. The pain associated with such an injection was enough to make me feel as though I would pass out.

The homeopathic treatments consisted of injections of various substances given to the brain stem, upper shoulders, the armpits, pectoral region, and the entire abdominal area. These various liquid solutions caused searing burning pain wherever applied and nausea shortly thereafter.

When I first witnessed another patient receiving these injections, I feared I would not be able to get through the treatment. I still wonder how I survived it. It was unspeakably painful.

Several days into my stay at the clinic, Dr. Rothschild dropped a bomb on me. He admitted that I may not be HIV-negative when I finish my treatment. However, he insisted that I would feel well enough to advocate this treatment for other individuals in the United States.

The price tag for subsequent patients coming into the clinic would be in the neighborhood of \$25,000 each. I suddenly understood why I had been brought there. It was a crushing reality.

Several days later, I decided that I had to get out of there. Dr. Rothschild made it very difficult for me to leave and I felt as though I were a prisoner for some time. However, I finally convinced some of the kinder staff members to arrange for me to get to an airport and purchase a ticket home. As I speak little Spanish, they were a lifeline to me.

Gentlemen, this experience has caused me a great deal of pain. Emotionally, the idea of being lied to as to the outcome of my treatment really hurts. Physically, the pain of the treatments themselves caused much distress to my body.

I must also take into consideration here the setback of not having the benefit of my prescription medications during the treatment period.

Financially, the outlay of funds associated with traveling to Mexico has caused undue hardship to me.

These events have been burned into my memory and will not soon be forgotten.

I thank the members of this subcommittee for bringing attention to fraud aimed at PWA's such as myself. I welcome any questions that you might have.

Mr. SCHUMER. Thank you, Mr. Payne.

Mr. Koontz.

STATEMENT OF THOMAS G. KOONTZ, EXECUTIVE DIRECTOR, MANHATTAN CENTER FOR LIVING, NEW YORK, NY

Mr. KOONTZ. Good morning. My name is Tom Koontz. First, Chairman Schumer, I would like to thank you very much, the other members of the subcommittee, and Mr. Dan Cunningham for inviting me to speak here today.

I am here today as the executive director of one of our Nation's largest AIDS service organizations, the Manhattan Center for Living. As the center's chief administrator, I have helped establish direct nonmedical support services for more than 3,000 metro New Yorkers living with HIV and AIDS and also services for their families, friends, partners, and caregivers.

But today I come here to relate my experience with scam artists who prey upon the HIV/AIDS community. Before I delve into my personal experience, though, I would like for you to allow me to give you the background on how I became involved with one of these scams, which is also Mr. Vollmer.

The Manhattan Center for Living is a volunteer-based organization founded upon the philosophies of the mind-body connection to improve a person's outlook. Consequently, we are concerned with the quality of a person's life after they have received the diagnosis.

Since 1988 the center's mission has been clear: to provide positive choices for our clients enabling them to take an active role in their own wellness and state of being. Manhattan Center for Living offers psychological counseling, support groups, health-positive workshops, massage therapies, and exercise classes. We have a foods project that educates our clients about the importance of diet, serving over 100 meals every day. The center's outreach program makes all of our services available to anyone who is home or hospital-bound.

Unfortunately, the reason I give you this background is the center's visibility and success and its very large HIV/AIDS population that "sure cure" scam artists are drawn to our clients.

Last fall I received a fax, of which everyone has a copy, which I read: It reads "HIV-positive to HIV-negative in 30 days." This was not only faxed to me, but it was faxed to most of the major AIDS service organizations in New York and was posted as a bill-

board around the East and West Village. I immediately responded to this and there is also a copy of my response letter—although it gave no person to respond to, just an address in Brooklyn.

In 3 days, I was contacted by a Mr. Richard Vollmer, who wished to meet with me and discuss his cure. It was during this first visit that he outlined this clinic that he had established, supposedly in Monterrey, Mexico, to provide a series of therapies which did include ozone and many others which he claimed were developed and tested in Puerto Rico.

When I questioned Mr. Vollmer for some statistics or for some verification of the validity of these therapies, he was not able to provide any verification.

He immediately expressed an urgency of a desire to work with me because of my influence with the client base at the center. A very interesting side note is that after a long conversation with Mr. Vollmer, as he left our initial meeting at the center he slipped a dirty hundred dollar bill into my hand, quote, "for the good work that we were doing at the center."

I asked for a copy of his protocol. He did fax me a copy of the protocol, which is the list of his proposed treatments. I immediately contacted my friend, the executive director of the Community Research Initiative on AIDS, to investigate the validity of his clinic. CRIA is a New York-based operation that does extensive testing for potential AIDS therapies in the United States.

Not only did they know of Mr. Vollmer, but they referred me immediately to Mr. Mark Green of the New York Department of Consumer Affairs.

Vollmer and I had several subsequent telephone conversations. A transcript of the last is also included in the package that you have. In these conversations he went so far as to suggest that he would establish a private clinic exclusively for the use of the Manhattan Center for Living, charging the center a slightly reduced set fee for treatments which then we could mark up however high that we wanted and use it as a fundraising tool for the center.

He offered me free travel to Mexico to see the clinic in exchange for my endorsement, which he stated would also lead to my becoming his national spokesperson. He also offered me a generous, ambiguous six-figure side income to funnel clients to his clinics in Mexico.

Of course it was already obvious to me that his interest was focused on the profit potential he could gain from those most devastated by the HIV virus.

I specifically asked Mr. Vollmer what he intended to do about the very large HIV population who had been dealing with this disease for a very long time and consequently had depleted their funds or their resources. He very bluntly, as in the records that you can read, said he was not remotely interested in these people.

He was interested in having me be able to reach out to those who could in quotes, "mortgage their homes and pay as much as \$100,000" for his cure. The price, anything above \$20,000 was negotiable if in fact they had the resources to pay more.

It was in cooperation with Mr. Green's office that our last conversation was recorded. Their investigation subsequently led to his indictment and trial, and Mr. Richard Schrader from the New York

Department of Consumer Affairs Office will be explaining these details to you later.

Because of the social and political stigmas surrounding HIV and AIDS, those who are infected are particularly vulnerable and susceptible to these scams. The desire to reverse a diagnosis of this infection can be overwhelming. What I have noticed from my client base and in my own case is that especially after an initial diagnosis a person will do anything to have this diagnosis reversed and will go to any expense, regardless of what it is.

Untested or fake treatments are particularly insidious because they have another side to them, something which Vollmer also put to me. They imply an FDA unwillingness or disinterest in providing a cure which in every case is their cure, spreading a distrust and fear within the HIV community toward the Government doing anything for them in their plight.

As we all know, there are many options that do improve the length and quality of people's lives living with AIDS. There are no proven cures to this devastating illness yet.

This is why those willingly and actively seeking to profit from false and untested cures must be stopped, in my opinion. A clear message needs to be sent to discourage these people who believe that the human condition is of lesser importance than the condition of their pocketbooks.

I strongly support any action this committee takes to protect the HIV/AIDS community from charlatans who destroy hope while stripping those living with HIV of the resources they vitally need, not only to survive longer but with dignity.

It is my belief that we must as a country rally on all fronts—medically, financially, politically and socially—to protect those facing AIDS until such a time that we find a cure for this disease.

I would like to thank you for your time, for your attention, and most importantly for your action.

[The prepared statement of Mr. Koontz follows:]

PREPARED STATEMENT OF THOMAS G. KOONTZ, EXECUTIVE
DIRECTOR, MANHATTAN CENTER FOR LIVING, NEW YORK, NY

Good afternoon. My name is Tom Koontz. First, I would like to thank Chairman Schumer, all of the members of this very important subcommittee and Dan Cunningham for inviting me to speak today.

I am here as the Executive Director of one of the country's largest AIDS service organizations – The Manhattan Center For Living. As chief administrator, I have helped establish direct non-medical support services for more than 3,000 people living with AIDS and HIV, including their families, friends, partners and caregivers. The daily challenges these people face are indeed vast and pernicious.

I've come here today to relate my experience with "scam artists" who prey upon the HIV+/AIDS infected community.

But before I delve into my personal experience, please allow me to give you the background behind how I became involved with one of these "scams." The Manhattan Center For Living is a volunteer-based organization which was founded upon the philosophies of mind/body connection to improve a person's outlook and consequently their quality of life.

Since 1988, the Center's mission has been clear; to provide positive choices for our clients – enabling them to take an active role in their own wellness

and state-of-being. We offer psychological counseling, support groups, health-positive workshops, massage therapies, and exercise classes. Our Whole Foods Project educates our clients about the importance of good diet, serving healthful meals to nearly 100 people each day. And the Center's Outreach Program makes nearly all of our services available to those who are home or hospital-bound.

Unfortunately, it is because of the Center's success and its large HIV+/AIDS -concerned population that "sure cure" scam artists are drawn to our clients.

Last fall, I received a fax at the Center touting a cure to HIV+/AIDS infection. Being at the forefront of medical and non-medical HIV related reports, I responded to the advertisement which read "HIV positive to HIV negative in thirty days." A copy of this FAX has been included in your package, along with my initial response.

In three days I was contacted by Richard Volmer, who wished to meet with me and discuss his "cure." It was during this first visit that he outlined the "clinic" he had established in Mexico to provide a series of procedures and therapies which were developed and tested (though unverified) in Puerto Rico. He expressed with urgency his desire to work with me because of my potential influence with the Center's client base. As he left our initial meeting,

he placed a hundred dollar bill into my hand "for the work being done by the Center."

As soon as I received a copy of his protocol – a list of his proposed treatments – I contacted the executive director of the Community Research Initiative on AIDS to investigate the validity of his clinic. CRIA does extensive testing for potential AIDS therapies in New York. CRIA only knew of Mr. Volmer, but referred me to Mark Greene at The New York Department of Consumer Affairs.

Mr. Volmer and I had several subsequent phone conversations. A transcript of the last is also enclosed in your package. In these conversations he went so far as to suggest he would establish a private clinic exclusively for The Manhattan Center For Living – charging the Center a set fee for treatments which could then be "marked-up" as a fund-raising tool. He offered me free travel to Mexico in exchange for my endorsement which would also lead to my becoming his national spokesman. He further offered a generous six-figure side income, for which I was to funnel clients into his clinics.

It became increasingly evident that his interest was focused on the profit potential he could gain from those most devastated by the virus. Volmer stated that he wasn't interested in those who had depleted their savings trying to combat HIV, but rather to

reach out to those who could “mortgage their homes and pay as much as \$100,000 for his treatments.” It was in cooperation with Mr. Greene's office that our last conversation was recorded. Their investigation led to his indictment and subsequent trial – Mr. Richard Schrader of the Consumer Affairs office will explain these later.

Because of the social and political stigmas surrounding HIV+ and AIDS, those who are infected are particularly vulnerable – and susceptible to these scams. The desire to reverse their infection can be overwhelming. After an initial diagnosis, people will try anything – and often go to any expense. Untested and false treatments are particularly insidious because these opportunists *imply* FDA unwillingness or disinterest in providing “the cure,” – their “cure,” – spreading distrust and fear.

There are many options which do improve the length and quality of these people's lives, but there are no proven cures to this devastating illness – yet.

This is why those willing and actively seeking to profit from false or untested cures must be stopped. A clear message must be sent to discourage those who believe that the human condition is of lesser importance than the condition of their wallets.

I strongly support any action this committee takes to protect the HIV+/AIDS community from charlatans who destroy hope while stripping those living with HIV+/AIDS of the resources they vitally need to survive longer and with dignity. It is my true belief that we must – as a country – rally on all fronts; medically, financially, politically and socially – to protect those facing AIDS, until such a time that a cure is found and this devastating and cruel disease is stopped for good.

Thank you for your time, for your attention and, most importantly, for your action.

Transcript of the second conversation between Carl Vollmer of "Bio-Med," and Tom Keontz, Executive Director of the Manhattan Center for Living. 10/8/92

(Keontz calls)

Secretary: (unclear) Associates.

TK: Carl Vollmer, please.

Sec: Yes, who's calling?

TK: Tom Keontz.

(pause)

CV: Hello.

TK: Carl?

CV: Yes.

TK: Tom Keontz.

CV: Yes, how are you doing. Hold on just one second.

TK: Sure.

(pause)

CV: Okay.

TK: Sorry I'm just getting back to you, I've been awful busy the last few days.

CV: I'm--I'm very patient. And I'm sure that you have been busy, and I'm sure that you've been thinking a lot.

TK: Yeah. So, I've talked -- you know, I have a good friend -- well, a lot of friends, heads of other organizations like mine, and I've looked over the protocol, and, well, I have a few questions. When are you planning on starting the test, this "test run"?

CV: Two weeks.

TK: Two weeks?

CV: Well, whenever is convenient. The date is not cast in stone. The only thing that is cast in stone is that I've got to start selecting people. Today and tomorrow-- by Monday, Tuesday. I've got to know who's going, so they can make arrangements and I can make arrangements.

TK: Uh-huh.

CV: The doctor who will be treating you-- I'm going to bring her up-- I'm going to bring him up here, as soon as I've selected everybody, to meet with everybody so that they know what they're doing. And I have a contract, if you want me, I can read it to you, I can fax it to you, I don't know how much you want to tell these people where you are. You want to take two minutes, I'll read it to you.

TK: Okay.

CV: Hang on (pause). Now all I got to do is find my glasses, and we're in business.

TK: Okay.

CV: This agreement, made -- and of course we'll put today's date, or the day's date on it, day of, and whatever month -- between Bio-Med Incorporated, a Delaware Corporation with offices at 61 Metropolitan Avenue, Brooklyn, New York, and hereinafter referred to as the Spa; and whoever the volunteer is, who's address is --, who is hereinafter referred to as the Volunteer;

"Whereas, the Spa, which is engaged in the general business of the rehabilitation of its customers' health through certain protocols considered as alternative treatments for the HIV virus,

period not to exceed thirty days after his enrollment."

TK: Oh.

CV: The whole thing is thirty days. I don't want some -- (pause). My doctors -- now, I told you, I'm the money man, I don't know nothing about doctors -- they claim that in two weeks, you will be negative. Two weeks. But your immune system is zilch at that point. They want two weeks more to build your immune system to where it should be. With their protocol. That's all. That's what it says. Just says you have to stay there thirty days.

TK: Uh-huh.

CV: "Upon the conclusion..." Excuse me. (Inaudible -- to someone in the room, "you've gotta go down to 54th street ...") I got three businesses here (laughs). "Upon the conclusion of the Volunteer at the Spa the Volunteer at the Spa's expense agrees to make himself available for post-treatment medical examinations by such medical authorities as the Spa may deem necessary and agrees that such examinations and their results will be the property of the Spa, which the Spa has the unequivocal right to exhibit either on audiotape, videotape, or by any other means to promote the treatment."

"10) The Spa will permit the Volunteer the unequivocal right to leave the Spa at any time, with the understanding that on leaving the Spa, the experiment will have been terminated and the Volunteer will be returned at the Spa's expense to the Volunteer's point of origin."

"The Volunteer certifies that he has read the protocol and his signing this agreement signifies that the treatment has been explained to him and he accepts it at face value, with the understanding that the Spa has made no guarantee that the treatment will produce the desired result of HIV negative."

TK: Mmm.

CV: Thirteen. The Volunteer understands that the only guarantee that the Spa does offer is that the treatment in no way will be detrimental to the Volunteer's health. The Volunteer in signing this contract certifies that other than what has been stated above there have been no promises, pressures or other inducements offered to the Volunteer to get him to enter into this agreement and the Volunteer certifies that he does so of his own free will. In witness thereof the parties hereto have set their hand and their seal...

TK: And you'll have a notary republic and everything?

CV: Nah, we'll just have it witnessed.

TK: You told me that these guys had done -- there's a couple of questions I have, just bear with me. That they had tested this in Puerto Rico already? And it worked, or what?

CV: Oh sure. I have the results in my desk here. If you want to come over and see them, you're welcome to come to my business, take a taxi.

TK: So they documented as zero-converting from positive to negative in their tests in Puerto Rico. And you have that documentation.

CV: Yeah. The trouble with it, is I don't know who's there. You give me a piece of paper with a Puerto Rican's name on it and how am I going to know he's in Puerto Rico?

TK: So they didn't document it in the same fashion you're proposing

wishes to promote itself and its treatment to the general public, and whereas the Volunteer who has been diagnosed as HIV positive wishes to attend the Spa and receive the alternative treatment without having to pay the Spa's fee; it is therefore agreed and understood that the Spa will accept the volunteer for treatment and the volunteer agrees to attend the Spa in Mexico at the Spa's expense on the following terms and conditions:

1) Payments for the Volunteer's treatment will be in the form of the Volunteer allowing the Spa to document every step of the selection, preparation, actual treatment, and effectiveness of the treatment.

2) The Volunteer agrees that the documentation may consist of his name, his picture, his voice, on audiotapes, videotapes, written records and computer printouts, or any other material the Spa may choose to utilize that may contain the Volunteer's picture, records, and/or personal information relative to the HIV virus and the treatment.

3) The Volunteer agrees that the Spa has the irrevocable right to use this information in any manner, form, or format that the Spa chooses.

4) The Volunteer agrees to make no attempt to revoke the right of the Spa so long as the volunteer is HIV negative.

5) The Volunteer agrees to authorize the Spa to obtain any and all other medical records or diagnostic records concerning the Volunteer and to make available to the Spa all information in his possession concerning his past and present medical condition-- we gotta help these guys, you know --

TK: Right.

CV: "The Volunteer agrees to be tested, examined, and interviewed by a minimum of five separate and independent testing laboratories at the expense of the Spa prior to leaving point of origin.

TK: So there would be five what? HIV tests done in New York?

CV: Right. We don't want anybody to go down and come up negative, and everybody says, well, it was a put-up job; I want to say, well, wait a minute, don't talk to me, go to this laboratory, this laboratory, this laboratory. And they got samples of his blood before and when he came back. It's self-defense. Lemme see:

"The Volunteer agrees to be examined by the Spa, and agrees to live up to the protocol and subject himself to as many physical examinations as from time to time the Spa may require. The Volunteer agrees that after he has been diagnosed as HIV negative, or in remission from the HIV virus, he will continue with the protocol and will continue at the Spa for a period not to exceed 30 days after his enrollment. Gotta stay there 30 days.

TK: Wait -- but -- but doesn't that say that after you convert sero-negative --

CV: No, no, it says that the Volunteer agrees that after he is diagnosed as negative --

TK: After he's -- well, that would be a conversion, from positive to negative.

CV: Right.

TK: Then you're agreeing --

CV: No, no -- "or in remission, he will continue with the protocol -- just continue with the protocol -- and continue at the Spa for a

doing.

CV: You see what this says, video, audio, the whole schmeer. From the time we sit down with somebody and they agree to this, we're going to turn the camera on. They're going to tell us what condition they're in now, and how they feel. It's all going to be documented so if the guy changes his mind, and he's negative, I'm going to say to him, look you signed all these things, and here's your picture and if you don't like it, sue me. Which I don't think will happen, but look, the lawyers write all this stuff. I tell 'em what I want and I write it down and they correct it.

TK: Put it in legalese.

CV: I'm not a lawyer but I've been through hard knocks with lawyers, and the money, and on and on. Although I wrote this, the lawyers have checked it and they can't find nothing wrong with it.

TK: So how many people are you going to take down?

CV: I'm taking down three people at my expense. I'm taking down three people at their expense.

TK: So six people will be going altogether.

CV: Yeah. There will be six rooms, separate rooms, separate bathrooms. Facilities for six people. I have a commitment to one of your members.

TK: Really?

CV: .. He's going down.

TK: Okay. Okay.

CV: I've not selected anybody else yet.

TK: Okay.

CV: I understand that the director of the '... is coming down. Either ... or ... , don't quote me, he's gonna call me today. He is a friend of the doctor's.

TK: Oh-huh.

CV: See, the doctor is already treat one of his -- roommates. ... , who we already have the commitment to --

TK: There are licensed doctors in Mexico?

CV: Oh, yeah, I understand that, yes. If you agree to this -- and I wouldn't ask you to get on a plane until you've met this guy -- I'm going to bring him up here before you go down. You can back out at that point if you do agree and you don't like what you see, I think you will.

TK: You've met them?

CV: Oh sure, I've spent days and days grilling them. Grilling them. I can't get a handle on anybody, I want proof. You know, these guys asked me to raise them some money and I said, okay -- show me. Like you want to see -- show me. They introduced me to one guy who says he's been cured, and I don't doubt it. He's gone now, he was just -- passing through. They gave me stacks of paper with names that I can't read, some in Spanish, some in English, and that's all meaningless garbage as far as I'm concerned. I have to go to Puerto Rico and seek these people out, because they're out in the world, you know. I could spend three weeks trying to find one of them. Forget it. The clinic is down there, is scared to death that somebody is going to burn it down, and they don't want anybody to know, but they'll let me go to the clinic. It's a whole mish-mash --

TK: What do you mean, like the community being afraid that there's

people with HIV around?

CV: I think so. I think that's part of it.

TK: You have not seen the facilities down there?

CV: I got pictures of it right here, but they're fax pictures, and they're no good. I have an engineer -- I'm not stupid, and I'm not going to Mexico, I mean I haven't been. I sent \$40,000 down there and I hired an independent engineer to go down there and see there's not a vacant lot. He reports back to me and he says, very simply -- let me read it to you. My desk looks like the Third World War.

TK: So does mine.

CV: He writes back, one bathroom is 70%, one bathroom is 60%, the water tanks are on the roof. You know, things are being done right.

TK: What does that mean, one bathroom is 60%?

CV: We rented a six room house. And it had one bathroom, which is not satisfactory. We're building four new bathrooms.

TK: So you actually are building bathrooms onto this house.

CV: Oh yeah, we rented this house for five years, and this is serious business. We're building bathrooms, putting water tanks on the roof, we've rewired the house, and we're making --

TK: I only ask about this because there's places in Mexico where it can be pretty bleak.

CV: It's in Monterrey, the third largest city in the -- I want to tell you very simply, and I want to make sure everybody understands it and hears it from my lips: this is a deal where you're going to go to Mexico -- especially the ones that go at my expense -- and you're going to drink what they give you, and four fourteen days, you've got the protocol, you're going to drink the juice that they give you, and you're going to be locked in your room away from the food.

TK: (laughing) Food, booze and sex, I don't know.

CV: Well, whatever you did before, you ain't gonna do it down there. This is a severe, uh, regime. But, you know, we're playing for such big stakes. Anybody that doesn't want to do it, don't do it. Be my guest. I'll find somebody that does want to do it. And they're going to give you enemas. And they're going to give you ozone with needles, or with a suit, who knows what they're gonna do. The only thing I can tell you is when the doctor says to me, When I give this man a needle, I'll draw two needles -- two syringes -- and we'll lay them on the table. The man can pick the one he wants, and I'll take the other one. Now you can't get better than that. As far as I'm concerned.

TK: You know, the reason that I have all these questions is that that 30 day commitment -- you know I'm the director of the second-largest, or one of the largest AIDS-service organizations in New York City -- so it's a long-term commitment, and of course I have to discuss it with my board of directors as I make my decision.

CV: I understand that, and, uh, I don't know whether they're going to pay you or not, I'm not going to ask what kind of money you make, but can you survive for that thirty days? Is your rent going to be paid? If not, we'll help you with it. I want to do what it takes to get you. Because once you're done -- if this works on you -- I don't have to run around the world trying to prove myself anymore.

TK: Right.

CV: You're going to do it (laughs). A living proof is better than all these goddamn papers that I've got all over the place. (To another person in the room: "Yes, Robert? You need what? I thought you were using... (inaudible)...")

TK: So, we had talked about how everybody who goes down, whether they're a paying person or people in my situation, are going to be committing to a thirty-day time frame.

CV: Oh, yes.

TK: Are you going to do the same kind of contractual agreement with people who, say, will go down after we come back with real testimonials?

CV: Not really. Probably, but not mandatory. I'm going to send these first three down free, at my expense, because I've got to find out what I'm doing. I can't ask somebody to go down if I have no proof. These other people who are paying, I haven't talked them into it. They've talked me into letting them go. There's six people who are trying to talk me into letting them go. And I'm saying to them --

TK: How much are they paying?

CV: Twenty thousand dollars.

TK: And will that be the normal, afterwards?

CV: The deal I'd like to make with you --

TK: The only reason I say that is because so many people who are affected by HIV -- now it depends on a lot of variables, I mean it depends on how progressive the disease is in their system, and what not, but many people are financially devastated, so that's a big chunk of money.

CV: Whoa, whoa. You've got to understand two things right from the beginning. That this is not something for everybody. Some people are not going to be able to take advantage of this, but the proposition I'd like to make you is that if you will go down, at my expense, spend the thirty days, I will see that you are not hurt up here by not being paid. To some degree, I don't know what that is, you're going to tell me what that is. If it's \$20,000, forget it, if I've gotta pay your half of the rent for a month or whatever, then we'll work it out. When you're satisfied that this works at the end of thirty days, you're gonna come back and be a spokesman for me. I will do one more thing. I will build for your organization's exclusive use another one of these Spas. No charge, I'm not going to charge you for it.

TK: Out of the country? In the same place?

CV: Hey, if this could be done here legally, it would have been done here three months ago. That's not the consideration. You just can't use some of these things, whatever they do, here.

TK: Uh-huh.

CV: But I will build a six or eight room spa for your exclusive use, and I'm going to say to you: this is what it costs down there, to feed these people, I gotta pay the rent, I want a little, 3% of my investment or 10% of my investment, blah blah blah. the doctors and the nurses would be paid for and the medicines would be paid for. The only thing your organization would have to pay for, they should only have to guarantee that there would be six or eight people going down there at a time. That doesn't mean six in one

day, but we gotta keep the place full. And its gonna cost your organization \$5000 for this discussion, for the doctors and all the medicines and the service and everything else. We now have to add to that another \$4000 for the rent and the plane ticket down, and whatever. If you want to send people down for that amount of money, it's yours. I get my \$5000 and we're gonna treat 'em just like they paid \$20,000, but these people are going down exclusively for you, and you're gonna select 'em. Your job is to generate 'em. If you could get them from six organizations, or eight organizations, or maybe from within your organization. If you can't, then I have the right to fill up that whole, either with a \$20,000 patient who doesn't want to go to one of the other spas -- I'm going to build six or eight or ten or fifty of these if I have to -- but six or eight --

TK: Well if it works the demand would certainly be there.

CV: Well, I, well -- you live in a world where, uh, the money is tight, solely because if the money wasn't tight, they wouldn't be coming to you for help. I would assume.

TK: Well actually that's not true.

CV: Okay. See I have a great deal of -- I'll tell you, I'm the worst man in the world to front this organization. I want you! I got a couple of other people who are articulate and nice guys, and I have to tell you that I don't really want to be on 60 minutes as the sounder of this operation.

TK: (bursts out laughing)

CV: I don't mind signing the checks and putting the money up, but I want somebody, I'm a benevolent dictator, I run six companies here. You don't do what I want, you don't work here. If I don't like the price you're charging me for what I'm buying, I go somewhere else and buy it. I'm not a nice guy from the standpoint of what we're trying to accomplish. I'm a nice guy, but I don't want to spend my days fronting this operation. Huh. I would like you to do it, and make money doing it, I'm not asking you to do it for nothing. There's a role here for you anywhere you want. But the most important thing --

TK: As a spokesperson coming back HIV negative, it would be a salaried kind of thing?

CV: Of course! Of course! And a big salary. We think there are sufficient number of the three million people in the United States with HIV virus who would go mortgage their house and put up \$100,000. These are the ones that we're after. I'll be honest with you, I'm gonna build you a clinic. I'll build anybody that you bring into the program a clinic and they can pay us the \$5,000 and we'll perform the service. They want to feed the people, uh, there's a certain amount that we have to control. But there are other things that we don't. If they don't want to have television, they don't have to have television. If they want to charge \$5,000 additional to what we charge, and they want to put that into the organization, be my guest. I have no problem with that.

TK: Sounds like a fundraiser.

CV: I don't have any problem with that. I'll be honest with you, I want to use six or eight or ten of these as my legitimacy factor. I'm going to say to my customers -- not your people -- to my people, the guy in Hamburg and the guy in Canada -- who I know has

more money than God, who would have financed this whole deal if he'd known about it -- but I'm going to say to him, you can go down, we have an opening in June 1997 at this one open clinic down there, although, if you want to go tomorrow, it's gonna cost you this much money. You know, he's gonna say I want to go today, and I'm gonna say OK.

TK: Add, Pull out your checkbook.

CV: (laughs) I'm not going to deny those that you were referring to, the financially devastated, the opportunity to go.

TK: Now one of the things in the protocol, in the original fax that I got, asked specifically for HIV positive people who were asymptomatic. Do you have a reading on how this works with people who are symptomatic?

CV: No, I'm sending one boy down -- one of your guys -- who's got full-blown AIDS.

TK: His T-cell count is 5, and he's ready to jump off the bridge. It was an emotional experience, I wanted to take him in my arms and say, let's go! I can't do that with everybody I look at.

TK: So the clinic, you're still building on it and stuff, but it will be up and running before everybody goes down there?

CV: We'll give it to the end of the month. By the end of the month. The first guys can go down in a couple of weeks, but if some can't go down till the first of the month, there's nothing that says everybody's got to be treated the same moment. It would be easier, I presume, but it's not my problem.

TK: Are you pretty much isolated the entire thirty days, or are you able to--

CV: No, you've got the television, you've got the phone, if you want to talk to anybody at your expense, and after thirty days, or after a certain period of time, they talk about taking you on a tour of Monterrey, but they want to control you --

TK: They don't want you to go out and eat hot dogs.

CV: Right, or drink a little gin. Nothing's worse than somebody who has an alcoholic problem in addition to their other problems. That's what we don't want. At this point. At my expense. I'm sure that you're not an alcoholic, and I'm sure that you're willing to understand that we're playing for big stakes here. This whole thing started because when these guys asked me to help raise money I said, okay, what's the return on my investment? There is no return on the investment -- when we get this thing down pat, and they got their end of it down pat-- when we get this to the point that anybody can do this, and there's no secret to what they're going to do, if you want to open up your own clinic, you can't have my doctors, but you can have your doctors who are as smart as they are and you can do what you want. So there's no patentable item here. This whole deal is a service.

TK: In the protocol it says that there are injections. The only thing in the protocol that's not something that I have heard of is injections. Do we know what they are at all in advance?

CV: You'll be told what they are, I'm the last guy to tell you what they are.

TK: I have to ask the doctor that?

CV: You'll meet the doctor. His words to me were, if one of these

guys doesn't want to do it, he says. I'll take it and you can take the other one. Let me put you on hold just one sec.

(pause) Hello? Who's this?

TK: Tom.

CV: Tom, okay.

TK: I'm going to think a little more, then I'm going to be speaking to my board of directors today and tomorrow. I'm going to be out of town over the weekend, so I'll try to talk to you tomorrow.

CV: If you have any more questions, give me a call, and if your board of directors is what I think they are and they have as much respect for you as I'm sure they do, then I'm sure they'll give you the time off. And as I said, if they're not going to pay you, don't worry about that. We'll see that you don't lose your apartment, your parking space, or whatever it takes.

TK: Great Carl, I'll talk to you.

CV: Bye.

Mr. SCHUMER. Thank you and I want to thank all four witnesses. I think you have graphically exposed in detail what people are going through. Our second panel will talk about how widespread this is. Unfortunately, Mr. Looney and Mr. Payne, your cases are not isolated, and at least speaking for myself, it fills me with anger that these people would do this. They ought to be punished, and that's what we intend to do.

Let me ask a couple of questions to clarify parts of your testimony.

This is to Mr. Looney and Mr. Payne. What went through your mind when these people came to you? Did you have some idea that their cures would be quack cures? Just give us a little more, Mr. Looney, description of what leads you to be fleeced by these charlatans.

Mr. LOONEY. Well, Mr. Chairman, the thing that impressed me the most about these guys was that they were medical doctors with M.D. degrees.

Dr. Birds had a large practice right across from the Medical Center of North Hollywood.

Mr. SCHUMER. Right.

Mr. LOONEY. Where he was on staff. I don't think I would have given the time of day for a cure that had to do with something that appeared on the outside to be snake oil but these appeared to be caring, responsible physicians. They seemed to have the belief in them from each of the patients it seemed like something was really happening.

Mr. SCHUMER. Right.

Mr. LOONEY. My feeling was that the bloodwork results that they showed was impossible to ignore, that these people who claimed to have these high T-cell counts, one guy said that he had 1,400 T-cells, a high high-normal, and he looked as healthy as a runner or an athlete and in my case I had seen my numbers drop from a relatively normal 700 range down to 400 in less than 6 months.

Given that big of a drop for no apparent reason, I had no reason but to feel that that wouldn't continue, and I felt, you know, even though I didn't have the disease of AIDS that it could rapidly become that, given what I had seen, so it was with optimism and a feeling that I was dealing with people that were very caring and interested in our well-being.

Now we were told that this was legal. These guys actually told us that under California law that a physician could concoct a remedy of his own design if he felt it would help his patients, so when I went down to see Dr. Herman he was in his pool house behind his house, and, you know, of course being a thinking individual I wondered why is this man operating a clinic by a pool, but it had been explained to me that he himself had lymphoma and he was treating it and this was the reason he had given up his medical practice.

Mr. SCHUMER. What do you think of Herman now?

Mr. LOONEY. I didn't know at the time what I know now. I don't feel that despite the fact that he is a good actor, I don't feel that he ever was well-intentioned.

Mr. SCHUMER. Right.

Mr. LOONEY. And I think that it was purely about money and I think he saw, he and Birds saw us as a pasture of cash cows to be milked and when he got all our money, we were dead, pure and simple.

I mean how can you be prosecuted by a dead person?

Mr. SCHUMER. Do you think the penalties we're considering are too severe? The penalties we're considering are 5 years for the fraud, 25 years, serious bodily injury?

Mr. LOONEY. I think they are too mild.

Mr. SCHUMER. Too mild. Let me ask you this. You may have answered this one.

One of the things we are debating is whether, if someone dies from one of these cures, perhaps we should go to life imprisonment.

Mr. LOONEY. Definitely.

Mr. SCHUMER. Do you know people who have died from—maybe I should ask Mr. Henke this—of the great works of these two “out-standing” physicians. Have people died because of what they have done?

Mr. HENKE. I think that probably in one sense all of them will, and that is to say that whenever you lead a patient to forgo efficacious remedies in favor of inefficacious remedies you shorten their lives in that just as the recipient of a shot to the heart who lingers for a while before he dies, these AIDS patients will linger and then they'll die and they'll die sooner because of the AIDS fraud that's been leveled upon them.

If I understand your question, though, did any die immediately as a result of this and the answer is yes. I think one patient that Mr. Looney described by the name of Mark Snyder, who was the one who lay in his bathtub for 3 days before being discovered and then ignored by Dr. Birds with the rampant septicemia and then ultimately succumbed, I think the autopsy report in that case demonstrates that that was the result of the rampant infection.

Mr. SCHUMER. Would you, Mr. Henke, as an attorney, see any difference between what Dr. Birds did to Mr. Snyder, between what these doctors do and murder—just taking a gun and shooting somebody?

Mr. HENKE. It was originally thought that it might be charged as murder. I think that, if I can address the question this way—

Mr. SCHUMER. Go ahead.

Mr. HENKE. There were two prosecutions that were brought against Herman. One was by the Board of Medical Quality Assurance and the second one was a criminal prosecution initially for felony AIDS fraud.

The Board of Medical Quality Assurance prosecuted Birds to revocation of his license. They allowed Herman to relinquish his license instead of—in return for not prosecuting him. That allows him to go any other State in the country—

Mr. SCHUMER. So Herman is—I didn't know this—Herman is free now?

Mr. HENKE. Oh, yes.

Mr. SCHUMER. He did not receive any real punishment for this?

Mr. HENKE. He relinquished his license to the California Medical Board and he paid a \$10,000 fine when the prosecutors dropped down the charges from felony AIDS fraud, and we have a statute

for AIDS fraud in California, felony AIDS fraud to misdemeanor AIDS fraud.

This is the message that all of the AIDS fraud artists in California got and that is you're going to be prosecuted extremely rarely. This was the one and only AIDS fraud case ever brought. If you are prosecuted, the medical board will let you ply your trade in any other State in the country and the criminal prosecutors will allow you to pay a \$10,000 fine and move elsewhere.

Mr. SCHUMER. Did Birds go to jail?

Mr. HENKE. Neither went to jail.

Mr. SCHUMER. Neither went to jail.

Mr. HENKE. Neither went to jail.

Mr. SCHUMER. If you were the prosecutor and had more latitude, what would you charge them with?

Mr. HENKE. I would have charged them with murder and I think this was contemplated at one time and one of the purposes for my litigation is to achieve the deterrence of AIDS fraud in the way that these prosecutions have not and hit these people in their pocketbooks, and that is the purpose for punitive damages. It is punishment. It is to set an example to others who would do that same thing.

Mr. SCHUMER. California is generally considered to be pretty rigorous about these things. Why are they so lax?

Mr. HENKE. I don't know they are any more lax than anywhere else.

Mr. SCHUMER. Why is everywhere so lax?

Mr. HENKE. I think that I may create some enemies in this answer but I think it's something that has to be said.

When you pursue AIDS fraud as you are doing here, there are gray areas, there are black areas, there are white areas. There is an interest of AIDS advocacy groups to want to protect the gray areas—

Mr. SCHUMER. This one is not a gray area.

Mr. HENKE. This is absolutely not a gray area. In fact, I talked to the AIDS advocacy groups before I brought the action to make sure that this was the one that made sense.

On the other hand, I think that a lot of compromises are made that should not be made and I would urge that you put good faith in the wisdom that has gone into the FDA regulations.

It's been built over years through the experience of thalidomide and other—the 38 amendments, the 62 amendments. There is a lot of policy and a lot of thinking that went into that and it should not be easily compromised in this circumstance which, as Mr. Conyers indicated, is not all that different from the circumstance of cancer patients and things that FDA has been dealing with for many, many years.

Mr. SCHUMER. No question. We didn't come to this hearing through the issue of AIDS per se. We came to it through the issue of health care fraud.

Mr. HENKE. Yes.

Mr. SCHUMER. And it just so happens that this, what happened to people with AIDS also happens to cancer victims, happens to anybody with terminal illness. This spreads far beyond AIDS.

Mr. Looney, and then I have some questions for Mr. Payne and Mr. Koontz.

What did the Viroxan do to you? What were its negative side effects? Do you still have any of them today?

Mr. LOONEY. Yes. Initially the first mode of treatment was to give me a shot with a drug which is of the consistency of honey and you had to warm it up to room temperature and the shot had to be given with xylocaine because it was so painful that you needed to deaden the side where you gave the shot.

It produced an extremely painful lump. Notwithstanding the xylocaine, it still hurt.

Mr. SCHUMER. How big?

Mr. LOONEY. Almost the size of a golfball but not quite as high but the same overall diameter.

We were told that if you just rubbed the area and massaged it and exercised it, it would go away.

Actually, I wasn't ever told this until later when Dr. Birds and Dr. Herman apparently didn't agree with each other, and in an attempt to win me over, he told me that the tissue on my hips that was, you know, still there much later, was mummified, that it was muscle tissue that was dead, nonfunctional but it was preserved.

Mr. SCHUMER. Do you still have that?

Mr. LOONEY. I still have it.

Mr. SCHUMER. The people who did this to you are scoundrels. It's hard to believe that now they can go somewhere else and do this again. We are going to try to do something about it.

Mr. Payne, when you became interested in the ozone therapy—just one question, a little different than Mr. Looney's—this is just my own judgment and I may be wrong about this.

Even injecting Viroxan to all of us who are nonphysicians, it seems medically correct. That's a bad word but you know what I mean. It seems like something a doctor would do, use something even if it's thick honey, and makes painful bumps. But the ozone treatment has almost a surreal quality to it. It's almost as if Dr. Gyro Gearloose came up with this.

I am asking this question seriously. Did even at the beginning when you went down there to Monterrey, did it enter your mind that this was quackery? Just tell us why—

Mr. PAYNE. Well, first of all, I should say that the very premise of ozone—

Mr. SCHUMER. And you are not the only one. Let me just make clear to everybody that he's hardly the only one that's fallen for this. Ozone therapy is probably the widest AIDS quack cure.

Mr. PAYNE. Before I go any farther I should say I wish that I would have had the benefit of xylocaine when I had my injections.

To answer your question now, the premise of ozone is that once the ozone is exposed—or the AIDS virus is exposed to the ozone that it has a killing effect on it, much as if blood is exposed to the air, that the AIDS virus is killed in the blood when exposed to air. That's the same principle so it sounded that it could have some promise, you know, based upon that theory.

Something else that led me to believe that the people may have some credibility is that I was asked to take three independent blood lab tests before I left my home and these were to be held by

a hospital, a laboratory and two independent laboratories until I came back from Mexico and then the results from the four where the blood was actually frozen, the serum was frozen, and then the blood tests matched with that for both DNA testing and Western blot or Elysa testing. It was to be compared before and after, so until I was confronted by Dr. Rothschild and he made the statement that I might not be HIV-negative when I leave but that I would feel well enough, until that time, when I was actually in Mexico, I didn't seem to feel at that time that there was any problem.

Mr. SCHUMER. Is part of their ability to dupe people related to the fact that they make you fly at your own expense far away so you put up with it for a longer period of time?

I take it that all these people, being the charming people that they are, demand cash in advance too? Is that true? Is that true of your case, Mr. Looney?

Mr. LOONEY. No, sir. In fact, he billed my insurance company.

Mr. SCHUMER. Oh, yes, I forgot to ask you about that. I'll get back to that.

What about you, Mr. Payne?

Mr. PAYNE. Mine was strictly a situation of providing my own transportation expense to Mexico.

Mr. SCHUMER. And then he would do it because you were going to be salesman for this, right?

Mr. PAYNE. If you'll notice from the videotape that I provided earlier, the technical jargon that they used to explain it sounds as though there is, you know, some promise there but then you get into the hucksterism later on and it is kind of hard to separate those two, you know, when you take into consideration the earlier points they make.

Mr. SCHUMER. And you received the tape. The tape that we just showed was the one that you had received, is that right, or was it one just like it?

Mr. PAYNE. I received the tape, yes, and it was advocated by Mr. Vollmer as the same type of treatments that they were using.

Mr. SCHUMER. Who was the gentleman on the tape, do you know his name? Have you ever met him?

Mr. PAYNE. I really don't know. All I know that the tape is split up like enzyme labs and it's on the tape itself and I don't know who the physician or alleged physician is on the videotape.

Mr. SCHUMER. Right. Did the doctor administer the treatments to you and was there a doctor on duty at the clinic?

Mr. PAYNE. Part of the time. Dr. Rothschild, he gave the treatments I would say probably 40 to 50 percent of the time. His brother-in-law, Juan, the so-called registered nurse, he gave the rectal insufflations and ozone treatments the rest of the time.

Now I should say in all fairness to them that all homeopathic injections were given by Dr. Rothschild because they were put in such sensitive areas of the body.

Mr. SCHUMER. Did they take care to dispose of the needles from the injections?

Mr. PAYNE. Hardly. The needles were placed into a liner or a trash can lined with a plastic bag, syringes thrown in. They were set on the curbside when full. There were children, you know, play-

ing in this, you know, lower class residential section of Monterrey that could pick through these trash bags and they did actually pick through trash in the area and the trash from the clinic was no exception.

I think the biohazard from that is out of this world.

Mr. SCHUMER. OK, two more questions.

First, do you think there are a lot of people who are victimized who just don't tell anybody because they are embarrassed?

Mr. PAYNE. I'm sure that there are.

Mr. SCHUMER. Finally, these people just outrage me. What's happened to these Mengelists, this Rothschild, Dr. Rothschild? Is he still running his clinic?

Mr. PAYNE. To be honest with you, I really don't know. I would suspect just from a gut level feeling—I realize that has no bearing—but I would suspect from the amount of investment that Mr. Vollmer put into the clinic I would say that he would probably still be operating the clinic. Obviously there's no U.S. Government intervention with a clinic being where it's located, so I would imagine the clinic is still in operation.

Mr. SCHUMER. And Mr. Looney or Mr. Henke, are Birds and his compatriot, are they still doing this stuff?

Mr. Henke or Mr. Looney, whoever knows.

Mr. HENKE. Birds I don't believe is. He had his license revoked by California. I think it would be very hard as a result for him to get a license anywhere else in the country.

Herman is very actively involved out of Florida running the Viroxan scheme out of the Bahamas and Tijuana, Mexico. The drug is manufactured at the Kenya Medical Research Institute and he is using it on African patients in Kenya.

Mr. SCHUMER. Just one other question. I mean these people are obviously just shams, frauds. I used the word "Mengelists" and I don't think that's much of a stretch, considering the stuff they injected you with. But I agree with you, Mr. Looney, they're pretty much interested in just making money.

Why don't they just give you some pills and charge you the thousands of dollars? Maybe Mr. Henke or Mr. Koontz would have an insight into this too.

They went through the elaborate procedures—the ozone and the Viroxan. Why didn't they just give you pills? Wouldn't that be easier for them and easier for everybody else? Does anyone have any thought on that?

Mr. LOONEY. Yes. I'm not sure that Herman may have believed in what he was doing at some point. I don't know. It was an incredibly cynical—I found it very difficult to believe that this had been done to me.

Mr. SCHUMER. Right. That's right. Could you tell us a little bit about the insurance? I left that out. I think that is an important part.

Mr. LOONEY. Dr. Birds would take care of that. There was a point at which catheter became plugged up and it wouldn't take any fluid into the vein and what happened was that over a liter of fluid leaked under my skin and into my chest cavity and for a 6-week period I was almost blown up like a blimp 3 years ago.

I had to take 6 weeks off of work and upon return I had filled out my half of the State form and given it to the doctor. On his own he filled out the rest of it and gave me a diagnosis of lymphoma and this is how he had been billing the insurance company.

Mr. SCHUMER. This is Birds?

Mr. LOONEY. This is Dr. Birds.

Mr. SCHUMER. Why wasn't he prosecuted for insurance fraud?

Mr. HENKE. That would call for my speculation.

Mr. SCHUMER. I hope everyone heard what Mr. Looney said. He said he had lymphoma and billed the insurance company.

Mr. HENKE. This is also what the hospital did.

Mr. SCHUMER. The hospital did it too. Charming.

Mr. HENKE. The hospital, the AMI Hospital was right in the middle of this. I can give a number of examples of that, but in addition to going along with such therapies as vitamin C therapies, having the Voll machine, the electronic machine, hooked up to the anus of herpes patients in the hospital by physical therapists there, all of the nurses calling this man a quack—they're complaining up the administrative lines and the administrator with money on his mind not only tolerating this but promoting it by providing meeting rooms at the hospital for the solicitation and indoctrination of these patients, by discounting the hospital fees for the Viroxan patients to participate in this and then when it came to billing the insurers they couldn't bill it as an illegal AIDS drug for HIV patients.

What they billed it for, what they billed it as was chemotherapy for lymphoma.

Mr. SCHUMER. This is just unbelievable. It burns me up. I mean this is the closest I have seen to what the Nazis did to people in the concentration camps. But here their motivation is profit, not ideology.

Mr. HENKE. There's law that you may want to consider and that is international law pertaining to this including the Nuremberg Code of Medical Ethics in Human Medical Research and the Helsinki Agreement which in addition—

Mr. SCHUMER. Yes. What happened to the administrator? Nothing?

What is his name or her name?

Mr. HENKE. The administrator was Michael Weinstein, who actually got dumped for having dipped into the till at the Medical Center of North Hollywood for unrelated reasons.

Mr. SCHUMER. Unrelated but he has been prosecuted? He went to jail?

Mr. HENKE. No, not with regard to this. In fact, the hospital has not—I think probably the appropriate entity to look into them I think would be the accreditation of hospitals, the Joint Commission on Accreditation of Hospitals should really take a look at them and I really would recommend it, and take a look at whether they should be accredited.

Mr. SCHUMER. Have you written to them of your experience and asked?

Mr. HENKE. No.

Mr. SCHUMER. We will. You don't have to.

Mr. Koontz, first, do you have anything to add about some of the broader questions that we asked because you have had a lot of experience.

Mr. KOONTZ. Chairman Schumer, in the case of are these people intentionally doing this—

Mr. SCHUMER. Right.

Mr. KOONTZ [continuing]. Doing this for a profit motive only, I can tell you that a lot of, several of the—

Mr. SCHUMER. Vollmer clearly was.

Mr. KOONTZ. Well, several of the treatment modalities that Vollmer was suggesting to be a cure are treatment modalities that I would embrace as improvement of the quality of a person's life.

Now that's not necessarily—I mean maybe some of the homeopathic things he used were not administered correctly but taking of vitamins and correct diet and exercise and things like that are certainly things that he promoted to me that we would utilize.

I know a group—

Mr. SCHUMER. You wouldn't put ozone into that category?

Mr. KOONTZ. I personally wouldn't.

Mr. SCHUMER. Viroxan?

Mr. KOONTZ. I personally wouldn't but after exposing Vollmer, in New York City, I was contacted by a half dozen people who firmly believe that there is some validity to ozone, who firmly—they would do it for free. They are doing it for free in the State, that they firmly believe it has some kind of solution. I don't know that they are harming anybody but themselves.

It's when a person says that they are going to cure something, that they have no backup information, that they have no way of proving that they have done anything that actually proves it. You know, we don't care, quite honestly, Chairman Schumer, where the cure comes from. I don't care whether it happens in Mexico, whether it happens in France, or whether it happens in New York City, as long as people are working toward it and there's some validity behind the resources that they are using to show that there has been some sort of effort—

Mr. SCHUMER. What about these two cases? Was there any validity?

Mr. KOONTZ. None whatsoever. None whatsoever.

Mr. SCHUMER. Should they be punished?

Mr. KOONTZ. Absolutely.

Mr. SCHUMER. Strongly?

Mr. KOONTZ. Vollmer is still in Brooklyn. Actually his statement—

Mr. SCHUMER. I just saw his address. Thank God he doesn't live in my district.

Mr. KOONTZ. He actually made a statement on the news after we had exposed him to consumer affairs saying that, fine, if he couldn't operate in New York he would go someplace else.

Mr. SCHUMER. Yes. I saw the transcript. You went over the parts of the transcript I wanted to make sure were in the record but let me just ask you how often you come across these schemes.

Mr. KOONTZ. This was the most blatant.

Mr. SCHUMER. This was?

Mr. KOONTZ. I mean actually sending a fax to me at the center.

Mr. SCHUMER. How many faxes did he send out? I guess we'll ask Mr. Schrader that. He's the one who was involved in this.

Mr. KOONTZ. Most of the AIDS service organizations in New York received it, plus he had put them on billboards in all of the Village areas.

Mr. SCHUMER. Could you just elaborate a little further? We have a little bit of a dilemma here—it's not one that troubles me as much as it may trouble you, Mr. Koontz—do you worry that if we crack down on the kind of schemes that Payne and Looney talked about that it will have a detrimental effect on potentially beneficial treatments that are not sanctioned by the FDA?

Mr. KOONTZ. Yes. I think it's extremely important that there be a line drawn as to what, as definition as to the difference between the improvement of the quality of a person's life, because there are many things that will improve the quality of person's life that may not be necessarily FDA-approved to remove AIDS from the system.

There is no cure for AIDS and actually quite honestly, which is something that a lot of people haven't thought of, "HIV-positive, HIV-negative in 30 days," which is what he put around New York, this might not be such a good thing. Just because he has taken the HIV virus out of your system means simply the only test we have for the HIV virus simply show that we have built up the antibodies for it in our system. Once he has removed the antibodies, what does that expose us to?

So I think the important thing is that people who purport to have a cure that have no backup documentation, have never done any kind of testing, those are the people to go after.

People who are saying I can improve the quality, you know, at the center—

Mr. SCHUMER. That very simply is the difference between fraud and not. We are only trying to cover fraud here.

Mr. KOONTZ. Exactly.

Mr. SCHUMER. Speaking of fraud, I just thought I'd bring this—Mr. Henke had shown me.

Mr. Looney, this little device here, which if you take the top off looks sort of like a transistor radio, and the dials say such interesting things as purple, violet, blue, scarlet, orange, yellow—what is this, Mr. Looney, just for the record?

For the record it has a bunch of different dials on it and a lot of knobs and switches and then two things here that look like they are the things you put glasses in.

Mr. HENKE. In all fairness, I don't know whether he knows the answer to that question.

Mr. SCHUMER. OK, then why don't you answer, Mr. Henke.

Mr. HENKE. Other than he can say that one that was not too dissimilar to that was used by Valentine Birds in his practice.

Mr. SCHUMER. What did he do with it, Mr. Looney? I mean did they attach it to you? What was this? This is sort of medieval electronics here.

Mr. LOONEY. Well, these are similar to a device that he had in his office called a Voll machine.

Mr. SCHUMER. B-a-l-l?

Mr. LOONEY. I think it's V-o-l-l.

Mr. SCHUMER. Oh, V-o-l-l, OK.

Mr. LOONEY. He had a person he described as a consultant come in and connect you to electrodes and then he would go through, he would put in those wells in this device homeopathic remedies and measure your energy frequencies of the organs in your body and tell you which ones you needed and then the time it was done to me, he'd elicit maybe seven or eight of these remedies, homeopathic remedies, and the next thing I was told, well, OK, that's all there is for today.

They sent me to the office and gave me a bill for nearly a hundred bucks, cash, and I said, well, what do I need the most because I can't afford this.

Mr. SCHUMER. Right.

Mr. LOONEY. And he told me you need these two the most and so I paid for those and left but this is what he was doing.

Mr. SCHUMER. And he was taking organ frequencies, pancreatic frequencies, spleen frequency?

Mr. LOONEY. Yes.

Mr. SCHUMER. Pituitary frequency. He never showed you the colors, right?

Mr. LOONEY. No. I guess I should have found out whether they were AM or FM.

[Laughter.]

Mr. SCHUMER. I'm glad—you're the only one who is allowed to be humorous about it, you know, has the right to be somewhat humorous about this and that's good.

OK, I want to thank our entire panel here. I think you have graphically illustrated why we have to do something. Thank you.

Mr. LOONEY. Thank you.

Mr. HENKE. Thank you.

Mr. PAYNE. Thank you.

Mr. KOONTZ. Thank you.

Mr. SCHUMER. Would the second panel please come forward.

Our second panel is composed of three distinguished witnesses representing law enforcement agencies that are on the front line on the war against AIDS fraud.

Our first panelist, Dr. Randolph Wykoff, is the Director of the Office of AIDS Coordination at the U.S. Food and Drug Administration.

His Office is responsible for coordinating all AIDS-related activities within the FDA. Also with Dr. Wykoff today, although not testifying, are Mr. Terry Vermillion—he's the Director of the Office of Criminal Investigation, Mr. Michael Daniels—he is the Director of the Office of Enforcement, and Mr. Robert Spiller, the Associate Chief Counsel for Enforcement.

Our second panelist, Mr. Richard Schrader, is the acting commissioner of the Department of Consumer Affairs in New York City, the largest consumer protection agency in the country. He served as deputy commissioner within the department for 3 years before New York City Mayor David Dinkins appointed him to his current post.

Our third and final panelist is Mr. Richard Stephens. He currently serves as the acting U.S. attorney for the Northern District of Texas, which is Dallas and environs. He previously served as the chief of the criminal division in the U.S. attorney's office in Dallas.

Appearing with Mr. Stephens is Candina Health, an assistant U.S. attorney. Ms. Heath recently prosecuted one of the largest AIDS fraud cases brought by the United States to date.

I want to thank all of you for taking the time to testify here today. Your prepared statements will be presented into the record, without objection, and Mr. Wykoff, we'll begin with you.

STATEMENT OF RANDOLPH F. WYKOFF, M.D., M.P.H., T.M., DIRECTOR, OFFICE OF AIDS COORDINATION, U.S. FOOD AND DRUG ADMINISTRATION, ACCOMPANIED BY TERRY VERMILION, DIRECTOR, OFFICE OF CRIMINAL INVESTIGATION; MICHAEL DANIELS, DIRECTOR, OFFICE OF ENFORCEMENT; AND ROBERT SPILLER, ASSOCIATE CHIEF COUNSEL FOR ENFORCEMENT

Dr. WYKOFF. Thank you, Mr. Chairman.

The FDA appreciates the opportunity to address you today on this very important issue of health fraud.

When we consider the global devastation caused by the HIV pandemic and when we consider the fact that there is no cure and no vaccine either now or on the immediate horizon, it is entirely understandable that people with AIDS are desperate to have access to any drug that may help them.

At the FDA we recognize that for people with life-threatening diseases when they have no alternative therapies their very best hope may in fact be a promising but yet as unproven therapy and we are very dedicated to working to make those products available to them.

We have implemented a variety of mechanisms by which promising therapies can be made available to people but we still recognize that there will be people with AIDS who want to have access to products besides those over which we have some control.

Some of those individuals will go to their physicians, but others will go elsewhere, and some of those individuals who go elsewhere will become the latest victims in the history of health fraud.

In looking at how we regulate access to unapproved products, I think it is very helpful to see these products as falling on a spectrum. At one end of the spectrum is a situation in which you have a compassionate and knowledgeable physician who works with a dying patient and when they have no more acceptable medical alternatives they make a decision to try a promising but as yet unproven therapy.

The other end of that spectrum is a situation in which you have an unscrupulous individual who preys on the desperation of a dying patient and exposes that person to a dangerous or worthless product and solely for money. Those are the classic snake oil salesmen we have heard so much about today. Their actions are moral obscenities of the worst type.

Our challenge as a regulatory agency is to look at the entire spectrum and try to draw a rational line on that spectrum. We must be willing to allow access to promising products but at the same time we have an obligation to protect dying patients from unsafe and fraudulent products.

The process of drawing that line on the spectrum is not an easy one, as you can imagine and it is something that we are constantly

challenged to do. Just this week, as you know, we have issued a letter to some AIDS community leaders articulating some new concerns that we have. We hope that these concerns added to the ones there on that poster will better enable people with AIDS to identify when they are being exposed to fraud.

We also hope that these new concerns will help direct our enforcement action.

For the purpose of today's discussion, we have also brought with us what we feel are several examples of products that have clearly crossed the line between access and fraud. For those of you that can't see the bottle that I am holding, there is a large poster-size rendition of it there on the left.

This first product is a medically useless product and yet it claims right on the bottle to have a \$200 minimum value. More importantly, this product is reported to be a cure for AIDS and for cancer, a cure for AIDS and cancer provided the individual that takes it stops all other approved therapies.

These two drugs are licensed drugs. They are available from any physician in the country. Yet they were purported for sale by two doctors in Tennessee who claimed that they were a secret cure for AIDS, a secret cure for which they charged \$10,000 per course and recommended up to three courses and they are available from every doctor in the country.

This is a product that is essentially high dose hydrogen peroxide, and yet it has been claimed to be effective for peripheral vascular disease, cerebral vascular accidents, Alzheimer's disease, and 28 other diseases ranging from AIDS to athlete's foot.

This product, Mr. Chairman, is the notorious ozone generator that you have heard so much about today. This is the tube by which the individual purports to be able to—excuse me, the wrong tube—but you get the idea. You put ozone into their rectum or their vagina. Despite the fact that there is no medical evidence to support the efficacy of ozone, it has over the years been claimed to be a cure for AIDS and acne, cancer and constipation and just about every other disease you can think of.

The sad truth, Mr. Chairman, is that there is in this country today no shortage of people who are willing to expose dying patients to false hope, to poverty, and to very real danger—all for money.

We must be able to take action against these individuals and to do that we think we need two things.

First of all, regulatory bodies like the FDA need to have the law enforcement tools to make our job possible to enforce against these actions and secondly and perhaps more importantly, we need to have the willingness of the communities that are impacted by these frauds. Communities affected by AIDS must be willing to put aside their inherent distrust of government and recognize that if we are going to have any opportunity to stop health fraud in this country, we must do it together.

In conclusion, Mr. Chairman, we at the FDA are absolutely dedicated to making promising products available to people with life-threatening diseases but we are equally dedicated to making sure that those patients do not become the victims of the most despic-

ble predators in our country and that is the purveyors of health fraud.

Mr. SCHUMER. Thank you very much for your strong and, I think, right on the money testimony.

[The prepared statement of Dr. Wykoff follows:]

PREPARED STATEMENT OF RANDOLPH F. WYKOFF, M.D., M.P.H.,
T.M., DIRECTOR, OFFICE OF AIDS COORDINATION, U.S. FOOD AND
DRUG ADMINISTRATION

Mr. Chairman, I am Dr. Randolph F. Wykoff, the Director of the Office of AIDS Coordination and the Acting Associate Commissioner for Science, Food and Drug Administration (FDA). With me are Mr. Daniel L. Michels, Director of FDA's Office of Enforcement, Mr. Terrell L. Vermillion, Director of FDA's Office of Criminal Investigations, and Mr. Robert M. Spiller, Associate Chief Counsel for Enforcement. I sincerely appreciate the opportunity to address your Subcommittee on the important issue of health fraud and AIDS.

Let me state succinctly at the outset the philosophy guiding the Food and Drug Administration (FDA) in this area. We are committed to providing people with life-threatening diseases access to the most promising therapies. This commitment in no way diminishes our responsibility to be vigilant -- consistent with the consumer protection goals of the statutes we enforce -- to the potential for health fraud. We will draw the line, and indeed, will not tolerate anyone who would exploit the victims of these diseases for personal gain.

As you know, AIDS is a public health crisis that has resulted in the death of tens of thousands of Americans. It is a disease that is believed to be always fatal and, despite the fact that we have approved over a dozen agents for the treatment of HIV/AIDS and HIV-related conditions, there is no cure or preventive vaccine on the horizon. It is entirely understandable, then, that people with AIDS are aggressively seeking access to any

potentially promising therapy.

At the FDA, we have implemented a number of changes in order to provide people with AIDS the broadest possible access, through legal means, to promising products. While these changes have taken many forms, three bear mentioning today:

First, we have implemented a variety of mechanisms to expand access to promising investigational agents prior to approval. Through these programs, people who have not been helped by existing therapies can have access to the most promising, but as yet unproven, investigational drugs.

Second, we have implemented mechanisms such as accelerated approval that have made it possible for us to review and, where appropriate, to approve drugs for HIV and HIV-related conditions in record time.

Third, we have clarified and articulated a long-standing FDA enforcement policy for personal use importation under which individuals may import for personal use small quantities of unapproved drugs for the treatment of life-threatening diseases such as AIDS.

In all of these initiatives, we have worked closely, and communicated frequently, with people with AIDS and their

advocates. The underlying principle for these initiatives is the recognition that for people with terminal illnesses, who lack satisfactory alternative therapies, promising investigational agents offer hope. But access without appropriate safeguards against fraud may offer little more than false hope.

Earlier this week we sent a letter to all known AIDS buyers' clubs -- groups which facilitate patient access to drugs and other products purportedly useful in treating AIDS and related diseases. In this letter, we repeated our commitment to working with the communities impacted by AIDS to identify truly promising, but as yet unproven, products that could become available through legal means. We also indicated our willingness to allow continuation of the beneficial aspects of the personal use importation policy, as long as abuses of the policy are prevented. We have done this to provide people with AIDS with access to truly promising products while protecting them from the kinds of health fraud that are the mutual concern of this Subcommittee, the FDA, and the AIDS community.

In our letter, we also listed three areas where we believe that the line separating reasonable access to truly promising agents from outright health fraud is crossed.

First, we stated our belief that no one's well-being is served by having access to a product for a serious disease without the

active oversight of a licensed physician.

Second, we stated that promotion and commercialization of unapproved products, in our experience, are frequently characteristics of the kinds of deception and health fraud that expose people with life-threatening conditions to ineffective and dangerous products.

Third, we stated our concern about products that are manufactured at unknown sources or under unknown manufacturing conditions. These products have an increased risk of contamination, variable potency, and lack of quality assurance that represent a substantial hazard for individuals with serious diseases, particularly those with weakened immune systems.

Mr. Chairman, we realize a tension may appear to exist between our commitment to providing dying patients with access to the most promising products, and our responsibility to protect those very same people from dangerous and fraudulent products. We believe our approach -- allowing access under appropriate circumstances, while being vigilant against cases of outright fraud -- is sound.

To understand this, it may be helpful to envision the access to an unapproved drug as falling on a spectrum. At one end of the spectrum is a situation in which a knowledgeable and

compassionate physician has a patient with a life-threatening disease who has exhausted all approved therapeutic alternatives. The physician and patient make an informed decision to try a promising, but as yet unapproved therapy, which is used under careful supervision and controlled circumstances.

The other end of the same spectrum is where an unscrupulous person preys on the terminally ill patient and, for personal profit or self aggrandizement,,exposes that patient to a fraudulent product. This is the classic snake oil salesman, the financially motivated shark that feeds on the desperation of dying people. This is an obscenity all can recognize as a crime.

In making our enforcement decisions, we must draw a line on this spectrum. To this end, we must direct our enforcement activities towards those actions and activities that pose the greatest risk to the public health.

Let me give you some examples of what we believe are clearly egregious threats to the public health in which we have taken action.

"CanCell" is water that has been "energized" by a plant. It has been promoted to have a high cure rate for all types of cancer, plus diabetes, arthritis, lupus, and, more recently, AIDS. Several studies were attempted to evaluate the

product. However, none showed any therapeutic benefit. After an FDA investigation, the government filed a complaint for permanent injunction on February 21, 1989, to enjoin the purveyors from distributing CanCell.

FDA received a complaint about a "cure" for AIDS which was being promoted by two physicians in Tennessee. The physicians used the guise of a clinical investigation in an attempt to gain credibility. The physicians charged \$10,000 for each stage of a one to three stage therapy and told the victims to discontinue standard therapy. The physicians were administering drugs for which there was no medical basis to believe they would be useful in treating AIDS. While FDA conducted the investigation, we determined it would be the most efficient use of our enforcement resources to work with the State of Tennessee to put an end to the scam. The medical license of one physician was revoked and the other was told not to practice anything except psychiatry.

Ozone therapy has also been used to treat AIDS patients without any scientific data to support the agent's safety or effectiveness. Ozone therapy and ozone generators have been promoted in magazines and newspaper advertisements and in books, videos, and audio cassettes. The introduction of ozone into immunosuppressed AIDS patients without careful

study of probable toxicities places the patients at unreasonable and significant risks.

FDA is currently involved in litigation with some ozone generator distributors. Because the litigation is ongoing, we will not describe the details of those cases.

FDA obtained a permanent injunction against Vital Health Products, LTD, Muskego, Wisconsin, which was promoting and selling hydrogen peroxide products for, among other uses, the treatment of AIDS. These products were found to be both misbranded drugs and unapproved new drugs.

There have also been a number of cases of AIDS fraud accomplished by promoters making substantial unwarranted claims for otherwise relatively safe products. To stop the unsupported AIDS claims, though not necessarily remove the product from the market, we have responded with warning letters and other enforcement approaches.

Mr. Chairman, let me say that it is clear that there are people who are willing to expose dying AIDS patients to false hope, poverty, and very real personal danger, for their own personal gain.

We must work together to stop health fraud in AIDS and in all

serious and life-threatening diseases. The government must have the proper criminal law enforcement tools. For your information, I have appended to my testimony a description of FDA's current authority in this area.

The most important tool to stop health fraud is community vigilance. People seeking AIDS treatments or preventatives can protect themselves against fraudulent promoters by watching for:

Anyone who claims to be able to cure an incurable disease.

Promotions that include words such as "miraculous," "secret," "suppressed," or foolproof."

Experimental treatments that you have to pay for.

Products that have only testimonials and no scientific evidence.

Products that claim to be cures for multiple diseases -- especially cancer, AIDS, aging, and so on.

Products obtained and used without your physician.

Products that require individuals to discontinue standard therapy

All of us must have the commitment and mutual trust to help prevent dying people from becoming victims of fraud. The challenge is not simple. The answer is not easy. But the threat is too great to ignore. In order to succeed, we must work together to stop AIDS health fraud. People with AIDS deserve no less. We cannot halt the disease yet, but we can stop some of the cruel fraud on its victims, and help our population to concentrate its hope and spending on potential helpful therapies.

We, at the FDA, will leave no stone unturned to get truly promising treatments into the hands of people with AIDS. There is no greater challenge to the public health and consumer protection missions of our Agency than expanding access to genuine agents of hope, while ferreting out the hoaxes and shams.

Thank you for the opportunity to appear before this Subcommittee. I look forward to answering any questions that you may have.

May 27, 1993, Hearing

FDA's Health Fraud Authority and Enforcement Program

The Food and Drug Administration's (FDA) authority to help eliminate health fraud comes primarily from various provisions of the Federal Food, Drug, and Cosmetic (FDC) Act. For example, the FDC Act prohibits the introduction into interstate commerce of any food, drug, device or cosmetic that is adulterated or misbranded (21 U.S.C. §331(a)). The statute also prohibits the introduction into interstate commerce of an unapproved new drug (21 U.S.C. §331(d)). FDA can initiate court actions to seize violative products and injunctions to stop violative behavior (21 U.S.C. § 334, 332). Violating FDC Act provisions with intent to defraud is a felony (21 U.S.C. § 333(a)(2)). FDA, together with the Federal Trade Commission (FTC), also regulates the advertising and labeling that makes the products misbranded.

FDA has, over time, developed a strategy to make the most effective use of limited resources for dealing with products that represent health fraud. Until the 1960's, a common tool used by the Agency was criminal prosecution. Since then, the Agency has expanded its enforcement program to include the use of other administrative and judicial measures such as seizures, warning letters, injunctions, import detentions, administrative detention

of medical devices, and recently, under the Safe Medical Devices Act of 1990, civil penalties and mandatory recalls.

As part of the Agency's enforcement program, which includes routine inspections, FDA also investigates individual complaints, obtains information, and collects evidence regarding potential violations of the FDC Act. Decisions as to the significance of these findings and what action should result are made in accordance with established compliance policy, which reflects factors such as health hazard potential, extent of product distribution, nature of the misbranding, jurisdiction of other agencies, and available resources. Whenever possible, FDA also coordinates its investigations and enforcement strategies with other federal and State consumer protection agencies.

To complement the regular field force, FDA established an Office of Criminal Investigations (OCI) in March 1992 to focus exclusively on investigating potential criminal offenses. To accomplish its mission, FDA/OCI has recruited approximately 100 special agents from FDA and other federal law enforcement agencies. The success of our initial recruitment efforts has provided OCI with a diverse group of talented federal agents with an average of 12 years of law-enforcement experience. OCI's first three field offices opened in January of this year, and the remaining three offices will open next month. The Agency expects

the creation of OCI to significantly enhance FDA's ability to investigate health fraud, including AIDS-related fraud.

In addition, two years ago FDA's National Health Fraud Task Force launched a program to monitor suspected fraudulent AIDS products and therapies in the states most affected by the AIDS epidemic. A major emphasis is placed on providing support for existing State AIDS Tasks Forces. To date, six such groups have been established, in Michigan, Colorado, Texas, Georgia, Louisiana, and California.

Mr. SCHUMER. Mr. Schrader is next.

STATEMENT OF RICHARD SCHRADER, ACTING COMMISSIONER, NEW YORK CITY DEPARTMENT OF CONSUMER AFFAIRS

Mr. SCHRADER. Thank you, Chairman Schumer, for the opportunity to speak in front of your subcommittee.

Mr. SCHUMER. I want to thank Mr. Schrader for coming down. The record will disclose that his wife once worked for me long before he worked for the consumer affairs department.

Mr. SCHRADER. Long before.

Mr. SCHUMER. I think long before she was your wife—shortly before.

Mr. SCHRADER. Shortly before she was, when we were both very young.

AIDS fraud preys on the sick and dark times and clearly preys upon the sick, the scared, and the unwary. We found that out in New York City.

The key to good law enforcement is strong law and also the assistance of activists in the community, health community and gay community, and people like Mr. Koontz and Mr. Payne, who came forward and refused to be victims.

In 1990 we began to hear about some of the AIDS scams in New York City and the Dinkins administration brought up the first regulation, I understand the first in the country, to try to halt outright AIDS quackery.

We promulgated an amendment to our consumer protection law and if I could just read to you a couple of the requirements.

We were looking for proper disclosure from any product or treatment that purported to make whole, benefit, or improve the body's immune system, and among the requirements in terms of our broader disclosure would be full disclosure of the effects of this product or treatment on those individuals with HIV, who are HIV-positive; the need to state clearly that the product or treatment cannot prevent contraction of the AIDS virus; the requirement to have clear substantiation with scientific documentation of the value of the product or treatment including results of medical clinical trials and the obligation to make that documentation public upon consumer request.

That became law in our city in the spring of 1990.

Not long after that we began to respond to some complaints out there among consumer groups. Our first action was against a vitamin company called Alacer about packaging products. They were saying that their vitamin, Emergen-C, which is simply a vitamin supplement of vitamin C, could in fact inhibit the full-blown onset of AIDS. They couldn't substantiate this at all. We gave them a notice of violation and fined them and they took it out of their packaging and it is off their labels as of now.

The far more egregious complaint and more egregious scheme that we ran into was the Vollmer case which you have heard about today, and I'll just very briefly talk a little bit about our involvement in there as an agency in that case.

It came to our attention actually our receiving a fax from a gay group in New York City who had also been solicited by Mr. Voll-

mer, and you have already seen the fax as it came in. Let me just show it to you.

This was papered around several communities in lower Manhattan, and if you look at it, it's actually a textbook case of defying every aspect of our regulation, slightly artful in a sense because he hits just about everything we try to prevent.

He says on the top "HIV-positive to HIV-negative in 30 days." Of course, that's a claim about what he will be able to do in terms of preventing AIDS. That is a violation.

He talks about the doctors who are seeking three HIV-positives to undergo alternative treatment without discussing what the actual effect on people might be who are HIV-positive.

He describes in this short pamphlet, "All expenses will be paid" with possible employment for people as spokespersons if they are successful, and he suggests that they will be successful.

Mr. Koontz has described his taped conversation with Mr. Vollmer over the phone. Let me describe a few things Mr. Vollmer claimed in that conversation.

He said that his doctors would assure Mr. Koontz that in 2 weeks he would be HIV-negative, that the treatment would be in no way detrimental to the individual's health, the volunteer's health, that Mr. Vollmer has documentation of his treatments having successfully converted patients from HIV-positive to HIV-negative in Puerto Rico. When asked under investigation for some scientific background on that claim or some documentation of that claim, Mr. Vollmer had none.

Mr. Vollmer also claimed that he was taking three people down there at their own expense to go through this protocol, this medical protocol, and that these three people would be paying \$20,000 to \$25,000 for the privilege of going down to his Mexican clinic.

More importantly in my view, since I think it really encapsulates Mr. Vollmer's—both his MO and his overall intentions, he says to Mr. Koontz, "We think there are a sufficient number of the 3 million people in the United States with HIV virus who would go mortgage their house and put up \$100,000 for the treatment. Those are the ones that we're after."

So Mr. Vollmer, who is clear about his predatory intent, when we were able to move against Mr. Vollmer we cited him on 50 counts of violation of our regulation.

Mr. SCHUMER. These are civil?

Mr. SCHRADER. These are civil counts. We had three dozen or so copies of the pamphlet that either been put on posters in Greenwich Village, Manhattan, or had been faxed out to organizations or individuals in New York City plus the remainder of the violations that we cited that had to do with various kinds of claims that he had made to people individually.

We have had some problems in the investigation.

One is that we haven't been able to find a cash nexus. It's not clear if he's taken money from anybody yet. We suspect he has and we are continuing with our case. But I think, and this goes to speak of some of the issues that you have raised in your legislation—I think even if we are successful in terms of our ability to gain a relatively large punitive measure and penalty from Vollmer, it's on the order of \$25,000–\$50,000.

He may not have the money to pay or this may be the cost of doing business and, as Mr. Koontz suggested, Vollmer has threatened he'll go elsewhere to try to peddle his snake oil.

I think a combination of criminal and civil penalties is critical in terms of our battling AIDS fraud.

One last note: It is also clear to me that Vollmer is now underground.

The solicitations have stopped. The phony claims have stopped. Alacer Corp., the vitamin company that I discussed earlier, I think has quite willingly agreed not to advertise their false claim any longer so even the limited civil penalties have had some impact but I think the stronger combination of civil and criminal penalties is precisely what we need to go after what I think is a growing kind of scam and scandal.

Mr. SCHUMER. Thank you, Mr. Schrader, for your testimony and your good work.

[The prepared statement of Mr. Schrader follows:]

PREPARED STATEMENT OF RICHARD SCHRADER, ACTING COMMISSIONER, NEW YORK CITY DEPARTMENT OF CONSUMER AFFAIRS

Thank you, Congressman Schumer and members of this subcommittee for the opportunity to speak today. As a consumer official in your hometown, Congressman, I need not tell you the horrible toll the disease of AIDS has already had on our City. Let me tell the subcommittee about my agency's actions against the contemptible AIDS scams that have attempted to deceive New Yorkers, one of which we have already heard about today.

History provides us with antecedents of these contemporary frauds who prey on the sick in hard times. Recalling the plague-ridden London of his childhood, Daniel Defoe in the Journal of the Plague Year reported no shortage of what he called "quack operators" who, amid the horror, were willing to lure and deceive those in desperate need of relief from a dreaded disease.

The descendants of these 17th-century hucksters deceive and exploit people with AIDS in our City who have already endured enough pain and loss suffering through a modern plague. Because of this, the Administration of Mayor David Dinkins, enforcing the strongest law of its kind, has taken aggressive and effective legal action against some truly unconscionable deceptions.

In 1990, under my predecessor, Mark Green, the Department of Consumer Affairs developed the first regulation of its kind to halt the promotion of AIDS quackery. We amended the City's Consumer

Protection Law, which guards City residents against deceptive trade practices, to require proper disclosure for any product or treatment for sale in the City's five boroughs that claims to improve the body's immune system. The regulation, which is included here with my testimony (Exhibit A), instituted five requirements, stating that any product or treatment that purports to boost the immune system must: 1) disclose its effects on those individuals with HIV; 2) state clearly that the product or treatment cannot prevent contraction of the AIDS virus; 3) have clear substantiation with scientific documentation, including the results of medical clinical trials; 4) make that documentation available at the consumer's request; 5) advertise all disclosures in print no smaller than one-third the size of an ad's largest letters or numbers.

In the three years the regulation has been in effect, Consumer Affairs has taken action against several companies and individuals for violations. You have already heard about one of the schemes perpetrated by Carl Vollmer, a Brooklyn real estate broker -- with no medical credentials -- who papered Greenwich Village with hundreds of fliers last fall advertising "HIV(+) to HIV(-) in 30 Days" (Exhibit B). Our investigation uncovered that Vollmer may have been charging some people \$20,000 for an "AIDS-cure" regimen in Mexico -- one that involved a vegetable juice fast and ozone therapy which, according to Vollmer's literature, would be "administered rectally and by intramuscular injection."

Consumer Affairs worked closely with an AIDS advocacy center as we unraveled Vollmer's real plan. Crucial to our investigative work were Tom Koontz and the Manhattan Center for Living. Tom recorded a phone call between himself and Vollmer in which Vollmer promised Tom a "big salary" if he ultimately helped bring people with AIDS into his program. Vollmer boldly stated his predatory goals in striking terms on Koontz's tape. He said he was specifically looking for people who would be willing to mortgage their homes and put up \$100,000. Consumer Affairs cited him with over 50 counts of violating our AIDS reg.

A month before we cited Vollmer's scam, we took action against a vitamin company for a less egregious but equally deceptive claim. We charged a California company, the Alacer Corporation, with violations of the AIDS reg for claiming in a packaging insert that its "E-mergen-C" vitamin supplement could somehow inhibit the onset of full-blown AIDS. This popular powdered multi-vitamin that can be added to water is a perfectly acceptable source of vitamin C necessary for a healthy diet, but Alacer could provide no scientific data -- as the law requires -- to substantiate its claim that "ascorbate can check HIV infection."

These particular false claims and solicitations have stopped because of our efforts. Our monitoring of advertisements suggests future violators have been deterred, at least for now. Consumer Affairs and the Manhattan District Attorney continue the

investigation of Carl Vollmer. Alacer, the vitamin company, has been far more cooperative, agreeing to end its claims about "E-mergen-C" in a legal assurance signed with Consumer Affairs.

The Dinkins Administration does not want to stifle experimentation and innovation in the field of AIDS research. We believe that our regulation, which mandates honest consumer disclosure and the documentation of all claims, is better for all who are concerned with finding relief from this epidemic. In the months ahead, we will continue to police our marketplace and take action against those who would try to make a killing on AIDS.

EXHIBIT A

TITLE 6—DEPARTMENT OF CONSUMER AFFAIRS

§5-13 Advertisements Claiming to Boost the Immune System. (a) It is a deceptive trade practice to make a claim or to imply in an advertisement that the use of a product or treatment will boost, enhance, stimulate, assist, cure, strengthen or improve the body's immune system unless such advertisement discloses either:

(1) the effect of the treatment or use of the product on an HIV-positive person or a person with AIDS (Acquired Immune Deficiency Syndrome) or;

(2) that use of the products or treatment has not been proven to prevent primary infection with HIV, nor is to be a cure for AIDS, nor to extend the life or improve the health of an HIV-positive person or a person infected with AIDS.

(b) Any claimed effects of the treatment or use of the product on an HIV-positive person or a person with AIDS in an advertisement shall be deemed a deceptive practice unless such claims are capable of being substantiated by scientific documentation including, but not limited to, medical clinical trials, small scale and informal clinical trials, compilations of clinical data from patients or other clinical information. Such documentation must support any claimed effects of the treatment or use of the product on an HIV-positive person or a person with AIDS. All documentation must be made available at the request of a consumer.

(c) All disclosures and words of limitation or qualification as required by this section shall be written or printed in letters at least one third as high and one third as broad as the largest words or numbers appearing in the advertisement, but in no event in less than ten point type. In radio announcements, the disclosure or words of limitation or qualification shall be clearly spoken, and in television announcements they shall be part of the audio track and not merely part of the picture.

EXHIBIT B

7 HIV(+) to HIV(-) in 30 DAYS

Doctors seek 3 HIV(+)s to undergo alternative treatment and then become spokespersons upon successful completion.

ALL EXPENSES PAID, plus possible full or part-time employment for those selected. Must be able to travel for treatment. Contacts within HIV+ community a plus.

Send name, day/eve phone #, present employment status, and physical condition to:

500 Metropolitan Ave.
Suite 457
Brooklyn, N.Y. 11211

All applicants will be contacted and interviewed for this opportunity. Serious only, please.

Mr. SCHUMER. Mr. Stephens.

**STATEMENT OF RICHARD STEPHENS, ACTING U.S. ATTORNEY,
NORTHERN DISTRICT OF TEXAS, DALLAS, TX, ACCOMPANIED
BY CANDINA HEATH, ASSISTANT U.S. ATTORNEY**

Mr. STEPHENS. Mr. Chairman, Ms. Heath and I want to thank the subcommittee for the opportunity to appear before you and testify regarding the prosecution of an AIDS frauds case in Dallas.

Mr. SCHUMER. We want you thank you for coming.

Mr. STEPHENS. In addition to my testimony, we will have a written statement for the record.

Mr. SCHUMER. Without objection, it's entered into the record.

Mr. STEPHENS. Unlike some of the experiences we heard from the first panel, what I am here to discuss is a particular case of the fraudulent procurement of AZT and the dispensing of AZT, a very legitimate drug in the health care for AIDS patients by a legitimate pharmacy and a legitimate pharmacist.

It was about a year ago in June 1992 that the Apothecary, which was the pharmacy, and its owner and primary pharmacist Mary Elizabeth Forsythe, were all found guilty of a 15-count indictment that basically included in its many counts the fraudulent procurement of AZT and the wrongful dispensing of the AZT.

The Apothecary was sentenced to 5 years probation, a \$1 million fine, the \$581,702 in restitution to the Government.

The individual pharmacist and owner of the pharmacy, Ms. Forsythe, was sentenced by the judge to 56 months incarceration and jointly ordered to make restitution in the amount of \$581,702.

The Federal program which these defendants took advantage of and defrauded, known as the AIDS Drug Reimbursement Program, allotted \$30 million to the States to provide AZT to indigent and underinsured patients. Texas received a total of almost \$6 million of those dollars.

In a rather hastily devised program, the State of Texas contracted with pharmaceutical wholesalers to provide the AZT directly to the participating pharmacies. The participating pharmacies in turn dispensed the program AZT to AIDS patients whose applications had been approved by the State.

The guidelines permitted a maximum dispensation of 400 capsules of AZT per month per qualified patient, and then upon receipt of invoices from the participating wholesalers of the program AZT indicating shipment to each pharmacy, the State disbursed Federal funds to the wholesalers.

In our case involving the Apothecary, in March 1988, Ms. Forsythe contracted with the State to participate in the AIDS Drug Reimbursement Program and participated in the program for about 20 months until suspended in November 1989 as a result of an audit conducted by the State of Texas.

During the 20-month period only the Apothecary and the pharmacy of Parkland Hospital, which is Dallas County's public hospital, serviced the Dallas, TX, area in this program. In October 1989 the State compiled statistics on the ordering patterns of all of the participating pharmacies in Texas and found that the Apothecary consistently ordered the maximum amount of AZT for each patient per month. This was considered abnormal because a pre-

scription for AZT should reflect the patient's fluctuating tolerance with AZT.

Further audits showed that the Apothecary was continuing to order program AZT for patients long after their death. During the entire 20-month period, the Apothecary ordered excessive amounts of program AZT, order program AZT for deceased patients, dispensed program AZT to unqualified patients and billed insurance companies for the program AZT, all of which the Apothecary was receiving for free.

The graphic provided to the committee summarizes the aberrant ordering and dispensing of AZT by the Apothecary. Viewing that graphic, when the program AZT dispensed is subtracted from the program AZT ordered, there are some 317,848 capsules missing and another 100,000 or so capsules wrongfully dispensed to patients who should not have been approved for the program—all at a total cost to the Government of over \$600,000.

The potential profit to the Apothecary in charging patients and insurance companies the maximum commercial rate for the free program AZT approached \$1 million.

At the trial doctors testified that they had never prescribed more than 400 capsules of AZT within a 1-month period to a patient, while the Apothecary's records reflected dispensations of 800 and sometimes even 1,200 capsules to a single patient within a given month.

Many dispensations were not supported as required by a written prescription and some of the written prescriptions were altered. Many of the AIDS patients interviewed did not receive any AZT from the Apothecary or at least not the amounts suggested by the Apothecary's books and records.

Many patients denied signing the program application submitted by the Apothecary to the State department of health, and the patients acknowledging genuine signatures admitted to either signing the application in blank or applying to the program at the Apothecary's recommendation as a precaution in the event their insurance companies canceled them, all of which furthered the fraud on the Government.

There were unique problems, two in particular, that were encountered throughout the trial in this case. During the course of the investigation, we had witnesses who would have been good witnesses and who would have been brought into the case at trial and willing to who died long before the trial commenced.

Another problem was that there were AIDS patients, customers of the Apothecary, that were simply reluctant to come forward, cooperate and testify unless the Government could guarantee anonymity, which we attempted to do but could not.

Mr. SCHUMER. Thank you, Mr. Stephens.

[The prepared statement of Mr. Stephens follows:]

**PREPARED STATEMENT OF RICHARD STEPHENS, ACTING U.S.
ATTORNEY, NORTHERN DISTRICT OF TEXAS, DALLAS, TX**

Mr. Chairman and members of the Committee, I am Richard Stephens, Interim United States Attorney for the Northern District of Texas. I am pleased to have the opportunity to testify before you today concerning a specific case of health care fraud that was prosecuted by my office. In addition to my oral testimony, I have a written statement for the record.

PROCEEDINGS:

On December 19, 1991, a federal grand jury in Dallas, Texas returned a 15 count Indictment charging R.P.H. Consulting, Inc., a pharmacy doing business as THE APOTHECARY, Mary Elizabeth Forsythe, Mary Brigid Earthman, and Martha Claire Henry with various offenses surrounding the fraudulent procurement of federally funded AZT for AIDS patients and the subsequent wrongful dispensation of the AZT. The specific offenses charged included violations of 18 U.S.C. § 371 conspiracy, § 1343 wire fraud, § 1341 mail fraud, § 666 federal program fraud, § 1031 major fraud, and § 641 theft of federal property.

All four defendants were tried on May 8, 1992, and on June 9, 1992, the jury found THE APOTHECARY and its owner and primary pharmacist Mary Elizabeth Forsythe guilty of all counts. The minor defendants Earthman (a pharmacist) and Henry (an office manager) were acquitted. On October 20, 1992, District Judge A. Joe Fish sentenced THE APOTHECARY to 5 years probation, imposed a \$1,000,000.00 fine, and ordered the payment of \$581,702.00 in restitution, jointly and severally with Forsythe. The Judge sentenced Forsythe to 56 months incarceration, jointly ordered the payment of \$581,702.00 in restitution, and did not impose a fine.

PROGRAM BACKGROUND:

On July 11, 1987, public law 100-471, known as the AIDS Drug Reimbursement Program or the AIDS Drug Assistance Program allotted \$30,000,000.00 to the states to provide Retrovir (AZT) to indigent and underinsured AIDS patients. The U. S. Department of Health and Human Services divided the money among the various states according to the most recent statistics provided by the Center for Disease Control on living AIDS patients per state. Between August 1987 and August 1990 Texas received a total of \$5,877,913.00.

The Texas Department of Health, by and through the Texas Board of Pharmacy, contracted with pharmaceutical wholesalers to provide the AZT directly to the participating pharmacies. The participating pharmacies in turn dispensed the program AZT to AIDS patients whose applications had been approved by the Texas Department of Health. The guidelines set forth by the Texas Department of Health permitted a maximum dispensation of four hundred (400) capsules of AZT per month per qualified patient pursuant to a written non-renewable prescription. The Texas Department of Health dispersed the federal funds to the wholesalers upon receipt of invoices from the participating wholesalers for the program AZT shipped to each pharmacy.

OFFENSE FACTS:

Mary Elizabeth Forsythe opened THE APOTHECARY in October 1987. In March 1988 Forsythe contracted with the Texas Department of Health to participate in the AIDS Drug Reimbursement Program. THE APOTHECARY participated in the program for twenty (20) months until

suspended in November 1989 as a result of an audit conducted by the Department of Health and Human Services and the Texas Board of Pharmacy. During the twenty (20) month period only THE APOTHECARY and the pharmacy at Parkland Hospital (Dallas County's Public Hospital) serviced the Dallas Texas area. In October 1989, the Texas Board of Pharmacy compiled statistics on the ordering patterns of all of the participating pharmacies in Texas, and noticed that THE APOTHECARY, one of the few private pharmacies involved, consistently ordered the maximum amount of AZT for each patient per month. This was considered abnormal in that a prescription for AZT should reflect the patient's fluctuating tolerance with AZT. After conducting a comparison with THE APOTHECARY's patients and the death records from the Bureau of Vital Statistics, the Texas Board of Pharmacy determined that THE APOTHECARY continued to order program AZT for patients even after their death.

The audit conducted in November 1989 further revealed that during the entire twenty (20) month period THE APOTHECARY ordered excessive amounts of program AZT, ordered program AZT for deceased patients, dispensed program AZT to unqualified patients, and billed insurance companies for program AZT. The attached graphic summarizes the aberrant ordering and dispensations of THE APOTHECARY. The top line reveals the program AZT ordered - 976,200 capsules at a cost to the government of approximately \$1,437,386.04. The second line from the top reflects the program AZT dispensed, purportedly to approved patients. The bottom line

indicates the amount of AZT purchased by THE APOTHECARY from its private wholesaler for its private patients. The second line from the bottom shows the AZT dispensed to THE APOTHECARY's private patients, either for cash or by billing the patients' insurance companies.

If the program AZT dispensed is subtracted from the program AZT ordered, 317,848 capsules are missing. Another 100,000 or so capsules were wrongfully dispensed to patients who should not have been approved for the program. The missing program AZT and the wrongfully dispensed AZT cost the government approximately \$616,000.00. The potential profit to THE APOTHECARY when charging patients and insurance companies the maximum commercial rate for the "free" program AZT approached \$1,000,000.00.

OTHER OFFENSE FACTS:

Doctors testified that they had never prescribed more than 400 capsules of AZT within a one month period to a patient. THE APOTHECARY's records reflected dispensations of 800 and sometimes 1200 capsules to a single patient within a given month. Many dispensations were not supported as required by a written prescription and some of the written prescriptions were altered. Many of the AIDS patients interviewed denied receiving any AZT from THE APOTHECARY, or at least not the amount suggested by THE APOTHECARY's books and records. Many patients denied signing the program application submitted by THE APOTHECARY to the Texas Department of Health. And the patients acknowledging genuine signatures admitted to either signing the application in blank or

applying to the program per THE APOTHECARY's recommendation as a precaution in the event that their insurance companies cancelled them.

PROBLEMS ENCOUNTERED:

Many AIDS patients and customers of THE APOTHECARY died during the investigation. Although depositions were taken "under protest" to preserve testimony, pre-indictment depositions are not provided for under any current code sections. The questionable admissibility of the depositions caused the government not to seek their admission. Additionally, many patients and customers were reluctant to cooperate or testify unless the government guaranteed anonymity. The defense repeatedly argued that the potential damage resulting from the inevitable disclosure of the identity of AIDS patients substantially outweighed the prosecution. While we were able to strategically present the case using numbers to identify the patients, the Court allowed the defense to constantly refer to the names of the patients.

Mr. SCHUMER. I want to thank all three people for their testimony.

I want to read into the record the tips to identify fraud because one of the purposes of this hearing is to educate. They are: Cures for incurable diseases; miraculous secret, suppressed or foolproof treatments; experimental treatment that you have to pay for; a lack of scientific information effective—if it says it is effective against multiple diseases; and the lack of physician involvement.

We will try if we can, if you have a written sheet on that, just to add that into the record as well.

OK, my first questions are for Dr. Wykoff.

First, I would like you to be able to look at the legislation we have proposed. We have been working with the FBI on it, primarily, but I think it would be excellent to have FDA input, so if we could send it to you and get back some comments rather quickly, we would appreciate it.

Mr. WYKOFF. Certainly.

Mr. SCHUMER. The FBI, they're the ones that came to us, saying that there were great loopholes in the law and they needed help doing it.

Second, I want to ask if that first bottle—you don't have to bring the chart up—the CanCell. It obviously has, I think I read, a post office box at the bottom. That's where you should send your money or get a new prescription or whatever. It says—I can't quite read it—compounded by something, post office box so-and-so, so-and-so, Michigan.

Can you just go and find those people and arrest them or at least charge them and do you?

Mr. WYKOFF. Could I?

Mr. SCHUMER. Sure. If you want to bring up somebody, if you just identify yourself for the record.

Mr. SPILLER. I am Robert Spiller. I am one of the FDA's Associate Chief Counsel for Enforcement.

The purveyor of this has been enjoined and after injunction was found by the court to have violated the injunction and has been found in contempt.

Mr. SCHUMER. Civil?

Mr. SPILLER. Yes.

Mr. SCHUMER. So in general in these types of cases you have a civil remedy rather than a criminal remedy?

Mr. SPILLER. FDA's statute provides civil and criminal remedies. We frequently go first with civil and frequently that is enough.

Obviously when you have so many scams rising you don't know which one will become prominent enough to deserve the big resources required by criminal cases when they start.

Mr. SCHUMER. OK. My next question is how big, Dr. Wykoff, is this problem? How quickly is it growing?

Mr. WYKOFF. Well, health fraud is a tremendous problem. It has been for a long time.

Mr. SCHUMER. Yes, but I mean AIDS fraud specifically. Health fraud we know is huge and we are going to have several more hearings on different aspects of health care fraud.

Mr. WYKOFF. AIDS fraud is a major problem. It is growing.

Part of the difficulty in putting a price tag on it is, as you have seen, so many of the products claim to be for AIDS and cancer and Alzheimer's, so what we are seeing is that many of the traditional cancer frauds are now claiming AIDS as well.

Mr. SCHUMER. Right.

Mr. WYKOFF. It's been estimated that health fraud of this type is probably a \$40 billion a year industry of which the AIDS portion is between a \$1 and \$10 billion component.

Mr. SCHUMER. Mr. Vermillion, it is my understanding you are setting up a new Office of Criminal Investigations at the FDA.

Why was the creation of that Office necessary?

Mr. VERMILLION. Well, the creation was to put forth a new initiative within the FDA to specifically address serious criminal violations of the Federal Food, Drug, and Cosmetic Act.

Previously there had not been a dedicated unit of trained criminal investigators or special agents that focused solely on the violations of the Federal Food, Drug, and Cosmetic Act and the Federal Anti-Tampering Act so this initiative was in recognition that time dictated an internal enforcement office staffed by trained criminal investigators.

Mr. SCHUMER. Let me ask you, Mr. Vermillion, do you have any AIDS fraud cases before you and could you tell us about your efforts in that area generally?

I don't want you to of course reveal any specific facts that would compromise ongoing investigations or trials.

Mr. VERMILLION. I understand. Yes, we did start the Office of Criminal Investigations in March 1992.

Our first offices became operational in January of this year. Presently we do have operational offices in Miami, Kansas City, San Diego, Chicago, and metropolitan Washington.

As a result, we are fairly new out there, pursuing not only fraud cases but other types of criminal cases involving violations of the Federal Food, Drug, and Cosmetic Act.

Mr. SCHUMER. Do you have any AIDS fraud cases that are now—

Mr. VERMILLION. Yes, we do have some AIDS fraud cases under actual investigation and some in the preliminary stages. They range from product substitution to an unwitting AIDS patient, that is someone believing they are buying the approved drug and paying the normal prices or higher and they are actually being soda substituted unapproved drug without their knowledge.

Other active AIDS fraud cases involve ozone generation and ozone therapies, similar to the testimony you heard today. So there are multiple criminal cases involving AIDS fraud scams out there.

We do expect that as the AIDS crisis increases that the opportunists, the con artists, the crooks will divert their energies to the more lucrative area of the desperation of AIDS patients.

Mr. SCHUMER. OK. Let me ask both of you, if we enacted a new health care fraud statute in title 18 of the Criminal Code, would that assist the FDA in pursuing health care fraud investigations?

Mr. VERMILLION. Well, obviously we would have to look at the wording and the language as to how it would apply. As the committee is aware, our authority comes under title 21 of the U.S. Code.

Mr. SCHUMER. We know that.

Mr. VERMILLION. Many times our special agents do reach out and pursue title 18 charges along with the title 21 charges. What is difficult for our agents is that we must prove the elements of each of these different charges. This takes more resources and lengthens our investigations. If there were a broadly worded statute that specifically addressed health fraud, the FDA Office of Criminal Investigations and other agencies such as the FBI and the HHS IG's Office who also investigate health care fraud cases would certainly look toward a specific statute that we could point to that would specifically address health care fraud and health fraud specifically. I believe new legislation would be useful to combat these types of crimes.

Mr. SCHUMER. Good. OK. I thank both of you gentlemen.

So, Richard Schrader it's nice to have a constituent testify, and this one is a good one, too. Let me first ask you in your regulations, do you require that negative, potentially harmful side effects such as our two witnesses experienced in awful amounts, be disclosed?

Mr. SCHRADER. Yes. The wording there in our reg is that any kind of negative consequence or any effect, period, on a person who is HIV-positive has to be disclosed at the point of sale at the transaction on the product itself.

Mr. SCHUMER. Right, OK, and how about you, Dr. Wykoff?

Mr. WYKOFF. We have very specific regulations on the informed consent to inclusion in clinical trials, clearly.

Mr. SCHUMER. The next one, why haven't New York City or New York State done anything criminal? Do they have criminal laws on the books that they could use against Vollmer or others like him?

Mr. GREEN. We worked with Manhattan DA's Office on this case since the actual transaction took place in Manhattan, although Vollmer is a Brooklyn resident.

Clearly they were looking only at the fraud aspect in terms of what they could do as far as a criminal remedy and it is my sense that something stronger would be helpful.

There, as far as we know, I spoke to them 2, 3 weeks ago, they still have not closed the book on Vollmer's case either, so it's an open file still and if we hear from Vollmer again I think we're going to be more sophisticated this time around and know how to go about the investigation but I think we have driven them underground for now.

Mr. SCHUMER. Right. Let me ask you how big a problem are we facing with AIDS fraud, how fast is it growing from your point of view?

Mr. SCHRADER. It's certainly growing. At least we are more aware of it now than we were before we wrote our regulation and the regulation gives us a legal instrument to respond more quickly and more effectively to it.

What we are looking at over the last year though is really a series of much smaller kinds of failure to disclose cases or certainly less egregious types of scams than the Vollmer case.

One example. We are seeing a spate of newspaper advertising where a couple of health stores are quoting doctors that there is a Scandinavian cure, a health pill that basically turns out to be nothing more than sugar and vitamin C and that this will in fact also inhibit the onslaught of AIDS.

Most of the time we are able to move effectively and with relatively modest fines. We get those ads out of the print media, but there are more people doing it now than ever—maybe not at the Vollmer level, although I suspect that we are going to be seeing something like that again, short of some kind of criminal action against a bad operator.

Mr. SCHUMER. Right. Finally, Mr. Stephens. Mr. Stephens is our last witness today, so we'll be finishing up shortly, but his case obviously is different than the quack doctors type but it shows why we wanted it here is just to show the extent of the kind of fraud that can go on in this area and, Ms. Heath, if you wish to answer the questions as well, feel free.

First, let me ask you this, isn't—you mentioned that sometimes they're asking for 800 or 1,200 dosage of AZT. Isn't that fatal or can't that be fatal? Ms. Heath.

Ms. HEATH. Yes. In fact, the 400 capsules of AZT has recently been reduced to 200 capsules of AZT. We do not believe the patients were taking that.

Mr. SCHUMER. No, I understand.

Ms. HEATH. We understand that most of the records of the Apothecary had been altered and there were some patients that did admit that they received more than 400 capsules within a given month but they were attempting to potentially stockpile some of the drugs in the event that the program had ended. There were rumors sometimes that the program would end and they would no longer receive any AZT.

Mr. SCHUMER. Now I understand that while some patients paid in cash for their AZT, others had insurance coverage that paid. So, my question again, because we're concerned, of course, with the loss of dollars as well as everything else that is going on here, to what extent were insurance carriers overbilled in this case and was there any way for the insurance companies to have learned that they were being ripped off?

Ms. HEATH. The pharmacy did all the insurance billing themselves. Most of the patients appreciated that and from the patients interviewed, they indicated that they did not review their statements that they received from the insurance companies so they were not able to tell the insurance companies to what extent they had received the AZT, so I don't think the insurance companies would have known that the patients had either not received the AZT or that the AZT the patients were receiving was AZT received from the program and federally funded and not actually purchased by the pharmacy.

Mr. SCHUMER. Right.

Ms. HEATH. The pharmacy also billed the insurance company the maximum amount it could at all times, which was approximately \$998 for a 400-capsule per month.

Mr. SCHUMER. So had the insurance companies been totally vigilant in an ideal world, they might have caught this a lot sooner?

Ms. HEATH. Correct, but as it was they did not, they never suspected that there was any problem.

Mr. SCHUMER. I understand. You also mentioned that pharmacy was selling drugs to "dead people," quote, unquote.

How did you find out this was going on?

Ms. HEATH. The Texas Department of Health did a death match once they determined that the pharmacy continually ordered the maximum amount of AZT allowed per patient. When they did a death match they discovered that there were orders placed well after a patient's death, sometimes exceeding 6 months after a patient died.

When they interviewed the pharmacist, the pharmacist said they only would order the AZT a month after the patient had picked up the AZT so they are saying that their records revealed that the patients had actually picked it up and they would reorder.

In our case we showed approximately 16 patients that had received AZT well after 4 months after their death and on up to 6 and 7 months after their death.

Mr. SCHUMER. Well, we have a lot of work to do in this area and I appreciate your work on this, as well, Ms. Heath.

Finally, just one other question for Mr. Schrader, and that is other than Mr. Koontz, have you received other complaints about Vollmer?

Mr. SCHRADER. No, we haven't. Although we did hear from Mr. Payne, but we haven't heard anything about Vollmer now for several months. As I said, he's been driven underground. There have been no solicitations recently that we have seen.

Mr. SCHUMER. Right, OK. That's really it for my questions. My colleagues will have to read the transcript and I'm sure they will notice what went on here today.

Anyone else have anything final to say on our panel?

[No response.]

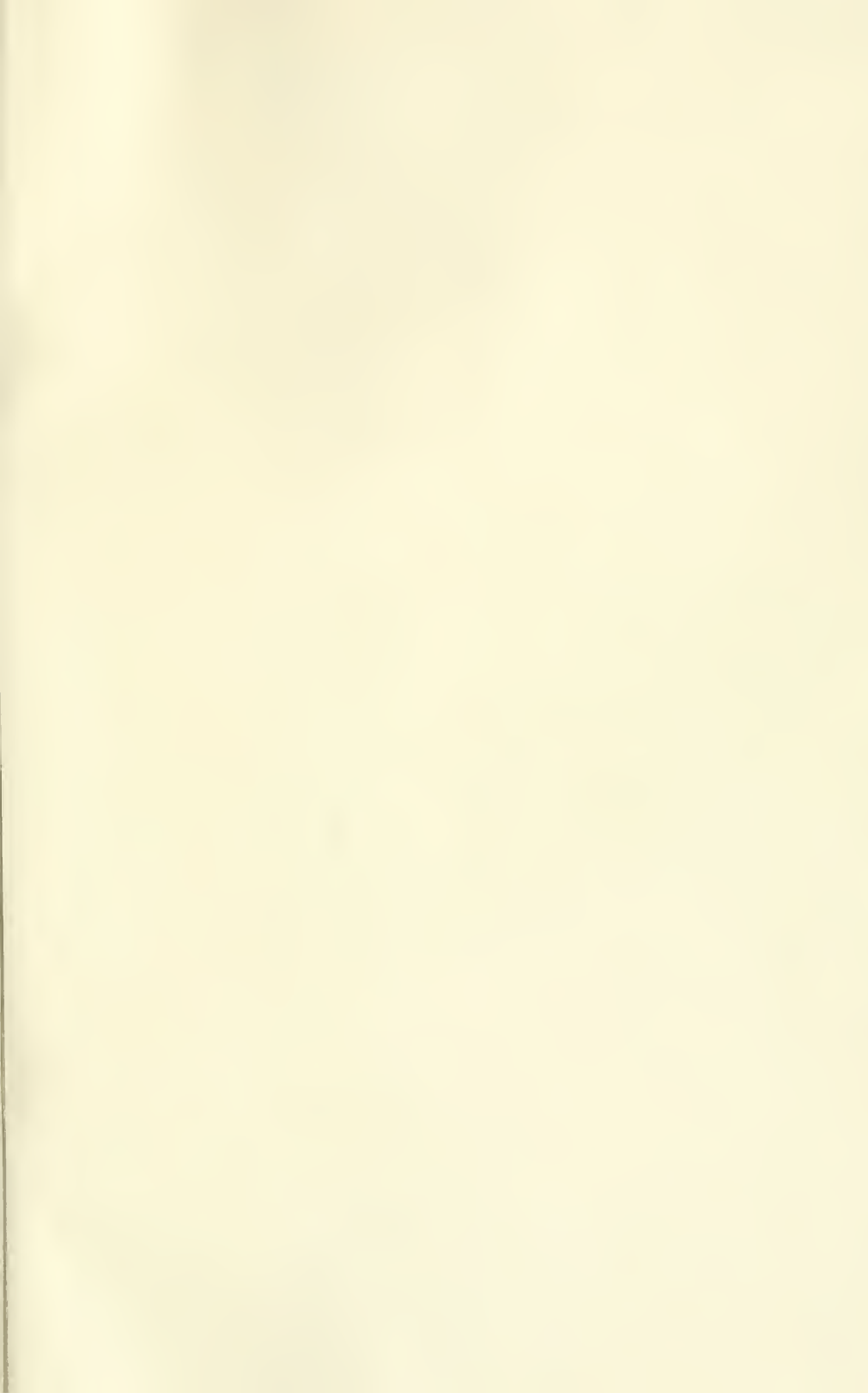
Mr. SCHUMER. OK, then I want to thank each of you gentlemen for being here today and in conclusion I just want to thank all of the witnesses for coming here and for telling their stories, particularly Mr. Looney and Mr. Payne. Obviously it wasn't easy but I think your testimony is going to give great impetus to our legislation.

I also want to thank my staff—Dan Cunningham really did a great job on putting this hearing together; Andy Fois is our subcommittee counsel; and Rachel Jacobson did a lot of the clerical work; and Mark Curtis helped out as well.

Finally I want to thank our stenographer as always, the unsung heroes of the hearing who sit there diligently transcribing away—Mark Mahoney, I thank you for your work. The hearing is adjourned.

[Whereupon, at 1:45 o'clock p.m., the subcommittee adjourned, to reconvene subject to the call of the Chair.]





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